

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE:

VIAGRA PRODUCTS

MDL DOCKET NO. 1724

LIABILITY LITIGATION

Judge John W. Borg

DEPOSITION OF:

NEAL A. SHER, M.D.

DATE:

February 13, 2009

TIME:

8:28 a.m. to 2:56 p.m.

LOCATION:

Parker, Waichman Alonso, LLP

27399 Riverview Center Boulevard

Bonita Springs, FL

TAKEN BY:

Defendant

REPORTER:

Deborah A. Krotz, CSR, RPR, CRR

VIDEOGRAPHER:

Gene Howell

| | |
|---|---|
| 2 | 4 |
| <p>1 APPEARANCES:</p> <p>2 For the Plaintiff's</p> <p>3 Steering Committee: ROBERT R. HOPPER, ESQ.</p> <p>4 Zimmerman Reed, PLLP</p> <p>5 651 Nicollet Mall, Suite 501</p> <p>6 Minneapolis, MN 55402</p> <p>7 Rrh@zimmreed.com</p> <p>8</p> <p>9 NEIL D. OVERHOLTZ, ESQ.</p> <p>10 Aylstock, Witkin,</p> <p>11 Kreis & Overholtz, PLLC</p> <p>12 803 North Palafox Street</p> <p>13 Pensacola, FL 32501</p> <p>14 NOverholtz@awkolaw.com</p> <p>15</p> <p>16 DANIEL E. BECNEL, ESQ.</p> <p>17 Becnel Law Firm, LLC</p> <p>18 106 West Seventh Street</p> <p>19 Reserve, LA 70084</p> <p>20 Dbecnel@becnellaw.com</p> <p>21</p> <p>22 For the Defendant: LORI B. LESKIN, ESQ.</p> <p>23 and AVIGAEEL FYMAN, ESQ.</p> <p>24 Kaye Scholer, LLP</p> <p>25 425 Park Avenue</p> <p>New York, NY 10022-3598</p> <p>Lleskin@kayescholer.com</p> <p>Also Present</p> <p>Special Master: JOHN W. BORG, ESQ.</p> <p>6612 Limerick Drive</p> <p>Edina, MN 55439</p> <p>Jwborg@aol.com</p> | <p>1 Sher Exhibit four-page editorial entitled 117</p> <p>2 No. 8 Non-arteritic anterior</p> <p>3 Ischaemic optic neuropathy and</p> <p>4 phosphodiesterase-5 inhibitors</p> <p>5 by Sohan Singh Hayreh 161</p> <p>6 Sher Exhibit 27-page document entitled</p> <p>7 No. 9 Appendix XII Sildenafil - 162</p> <p>8 Visual Summary</p> <p>9 Sher Exhibit 25-page document entitled</p> <p>10 No. 10 Viagra (sildenafil citrate)</p> <p>11 Tablets</p> <p>12 Sher Exhibit one-page document, an e-mail 169</p> <p>13 No. 11 from Neal A. Sher, M.D., to</p> <p>14 rrh@zimmreed.com, Subject:</p> <p>15 Retainer agreement</p> <p>16 Sher Exhibit two-page document entitled 174</p> <p>17 No. 12 Neal A. Sher MD FACS</p> <p>18 Consulting Work Log</p> <p>19 Sher Exhibit 33-page document entitled 185</p> <p>20 No. 13 Certification of Records for</p> <p>21 Richard Stanley from the St.</p> <p>22 Paul Eye Clinic</p> <p>23 Sher Exhibit one-page document Bates 204</p> <p>24 No. 14 labeled MARTIN R. FERRERA 0092</p> <p>25 Sher Exhibit 55-page document entitled 214</p> <p>No. 15 Deposition of Richard Martin</p> <p>taken August 5, 2008</p> <p>Sher Exhibit three-page document, an 220</p> <p>No. 16 excerpt from the videotaped</p> <p>deposition of Dr. Gerald D.</p> <p>McGwin, Jr.</p> |
| 3 | 5 |
| <p>1 INDEX</p> <p>2 WITNESS: PAGE:</p> <p>3 NEAL A. SHER, M.D. 6</p> <p>4 DIRECT-EXAMINATION</p> <p>5 BY MS. LESKIN: 229</p> <p>6 CROSS-EXAMINATION</p> <p>7 BY MR. OVERHOLTZ: 241</p> <p>8 REDIRECT-EXAMINATION</p> <p>9 BY MS. LESKIN:</p> <p>10 EXHIBITS</p> <p>11 EXHIBIT DESCRIPTION PAGE:</p> <p>12 Sher Exhibit 18-page document entitled 6</p> <p>13 No. 1 Curriculum Vitae of Neal A.</p> <p>14 Sher, MD, FACS</p> <p>15 Sher Exhibit five-page document entitled 22</p> <p>16 No. 2 Contents of CD labeled:</p> <p>17 Material Requested for Viagra</p> <p>18 NAION Depo</p> <p>19 Sher Exhibit 13-page document entitled 23</p> <p>20 No. 3 Expert Report of Neal A. Sher,</p> <p>21 M.D., FACS</p> <p>22 Sher Exhibit two-page document, and e-mail 27</p> <p>23 No. 4 from Neal A. Sher to Daniel</p> <p>24 Becnel dated May 27, 2005,</p> <p>25 Subject: Visual loss, CV and</p> <p>fee schedule</p> <p>Sher Exhibit five-page document entitled 65</p> <p>No. 5 Subpoena in a Civil Case to</p> <p>Neal A. Sher</p> <p>Sher Exhibit four-page article entitled 82</p> <p>No. 6 Hypothesis, A Venous Etiology</p> <p>for Nonarteritic Anterior</p> <p>Ischemic Optic Neuropathy, by</p> <p>Leonard A. Levin, M.D., Ph.D.,</p> <p>Helen V. Danesh-Meyer, FRANZCO</p> <p>Sher Exhibit four-page extended report 99</p> <p>No. 7 entitled Non-arteritic</p> <p>anterior Ischaemic optic</p> <p>neuropathy and the treatment</p> <p>of erectile dysfunction</p> | <p>1 THE VIDEOGRAPHER: For identification, this is</p> <p>2 the beginning of Videotape 1. My name is Gene</p> <p>3 Howell of Veritext National Deposition and</p> <p>4 Litigation Services. The date today is</p> <p>5 February 13th, 2009. The time is approximately 8:30</p> <p>6 a.m. This deposition is being held in the office of</p> <p>7 Parker Waichman Alonso, LLP, located at 27399</p> <p>8 Riverview Center Boulevard, Bonita Springs, Florida.</p> <p>9 The caption of this case is Viagra Products</p> <p>10 Liability Litigation versus Pfizer. The witness is</p> <p>11 Dr. Neal A. Sher. The court reporter is Debbie</p> <p>12 Krotz of Veritext National Deposition and Litigation</p> <p>13 Services.</p> <p>14 At this time, will counsel please state their</p> <p>15 appearances for the record.</p> <p>16 MS. LESKIN: Lori Leskin, Kaye Scholer, for</p> <p>17 Pfizer.</p> <p>18 MS. FYMAN: Avigael Fyman, Kaye Scholer, for</p> <p>19 Pfizer.</p> <p>20 MR. OVERHOLTZ: Neil Overholtz for the</p> <p>21 Plaintiff's Steering Committee.</p> <p>22 MR. HOPPER: Randy Hopper for the Plaintiff's</p> <p>23 Steering Committee.</p> <p>24 MR. BECNEL: Daniel E. Becnel, Jr., for the</p> <p>25 Plaintiff's Steering Committee.</p> |

2 (Pages 2 to 5)

| | |
|---|--|
| <p style="text-align: right;">6</p> <p>1 SPECIAL MASTER BORG: John Borg, the Special</p> <p>2 Master.</p> <p>3 THE VIDEOGRAPHER: Will you swear in the</p> <p>4 deponent.</p> <p>5 THEREUPON,</p> <p>6 NEAL A. SHER, M.D.,</p> <p>7 a witness, having been first duly sworn, upon his oath,</p> <p>8 testified as follows:</p> <p>9 DIRECT-EXAMINATION</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. Good morning, Dr. Sher. How are you?</p> <p>12 A. Morning, Ms. Leskin.</p> <p>13 (Sher Exhibit No. 1, 18-page document entitled</p> <p>14 Curriculum Vitae of Neal A. Sher, MD, FACS, was</p> <p>15 marked for identification.)</p> <p>16 BY MS. LESKIN:</p> <p>17 Q. I'm going to hand you what we've marked as</p> <p>18 Exhibit 1 to your deposition. I will give your counsel</p> <p>19 a copy.</p> <p>20 This is what was provided to us as your</p> <p>21 Curriculum Vitae. Is this, in fact, a true and current</p> <p>22 copy of that?</p> <p>23 A. It is the latest printed copy, yes.</p> <p>24 Q. Okay. You'll see in the upper left-hand corner</p> <p>25 it says updated November 2008?</p> | <p style="text-align: right;">8</p> <p>1 they recruited you to run?</p> <p>2 A. I developed it.</p> <p>3 Q. And the fact that it was sponsored by a</p> <p>4 pharmaceutical company, did that at all affect the way</p> <p>5 in which you analyzed the data?</p> <p>6 A. No. The data was analyzed by an independent</p> <p>7 statistician, and the results show that their drug and</p> <p>8 the competing drug were identical.</p> <p>9 Q. And did the fact that the trial was sponsored</p> <p>10 by a pharmaceutical company affect the way in which you</p> <p>11 collected the data?</p> <p>12 A. No.</p> <p>13 Q. Does your CV that we've marked as Exhibit 1</p> <p>14 otherwise accurately reflect your education?</p> <p>15 A. Yes.</p> <p>16 Q. And accurately reflects your professional</p> <p>17 training?</p> <p>18 A. Yes.</p> <p>19 Q. And other than the one change that we've made</p> <p>20 by adding your two Executive Committee appoint -- your</p> <p>21 Executive Committee and Patient Care Committee</p> <p>22 appointment, does it accurately reflect your</p> <p>23 appointments?</p> <p>24 A. To the best of my knowledge, yes.</p> <p>25 Q. And other than the one publication we've just</p> |
| <p style="text-align: right;">7</p> <p>1 A. Yes.</p> <p>2 Q. Have you added to your CV since that time?</p> <p>3 A. I have an article that was published this month</p> <p>4 that may have been on here as in press and -- about a</p> <p>5 drug -- a drug study that I did. And that's probably</p> <p>6 the only thing that is missing. There's a couple of</p> <p>7 committee assignments. I'm on the Executive Committee</p> <p>8 and the Patient Care Committee of the Phillips Eye</p> <p>9 Institute in Minneapolis. I neglected to put that down</p> <p>10 I noticed.</p> <p>11 Q. The article that you -- has now been published,</p> <p>12 what journal is that in?</p> <p>13 A. Journal of Refractive Surgery.</p> <p>14 Q. And what was the title of that article, to the</p> <p>15 best of your recollection?</p> <p>16 A. It is a trial of Zybrum and Acular for the</p> <p>17 control of post-operative pain after laser vision</p> <p>18 correction surgery, PRK surgery. I was the principal</p> <p>19 investigator.</p> <p>20 Q. And was that a study that was sponsored by a</p> <p>21 pharmaceutical company?</p> <p>22 A. Yes.</p> <p>23 Q. What company?</p> <p>24 A. ISTA, I-S-T-A.</p> <p>25 Q. And was that a study that you developed or that</p> | <p style="text-align: right;">9</p> <p>1 added, does it accurately reflect all of your</p> <p>2 publications?</p> <p>3 A. Yes.</p> <p>4 Q. What's the nature of your current practice?</p> <p>5 A. My practice has been in Ophthalmology, clinical</p> <p>6 practice with an emphasis on refractive surgery and</p> <p>7 corneal disease. I still do some general</p> <p>8 ophthalmology.</p> <p>9 Q. You're not a neuroophthalmologist; correct?</p> <p>10 A. I am not.</p> <p>11 Q. Is there a special -- Is there a certification</p> <p>12 for refractive surgery within Ophthalmology?</p> <p>13 A. There is not a formal certification such as a</p> <p>14 certificate.</p> <p>15 Q. Now refractive surgery, does that encompass</p> <p>16 really any type of laser surgery on the cornea?</p> <p>17 A. Yes.</p> <p>18 Q. And that includes what we know as LASIK and PRK</p> <p>19 and the various types; correct?</p> <p>20 A. That's -- that's correct, and some other</p> <p>21 procedures that are non-laser.</p> <p>22 Q. The only reason I know that is because I had</p> <p>23 the LASIK --</p> <p>24 A. Yes.</p> <p>25 Q. -- and my husband had the PRK, so --</p> |

3 (Pages 6 to 9)

| | |
|---|--|
| <p style="text-align: right;">10</p> <p>1 A. Who sees better?</p> <p>2 Q. I do.</p> <p>3 A. Good.</p> <p>4 Q. Do you also perform cataract surgery?</p> <p>5 A. I stopped doing cataract surgery about three,</p> <p>6 four years ago. I have done some thousands of them.</p> <p>7 Q. Is there a particular reason you stopped doing</p> <p>8 cataract surgery?</p> <p>9 A. I wanted to specialize more and devote more</p> <p>10 time to my -- developing my practice in refractive</p> <p>11 surgery. The -- the age groups somewhat diverged. And</p> <p>12 I enjoy the laser vision correction surgery more and</p> <p>13 decided might as well do what you like the most.</p> <p>14 Q. In looking over your CV, the articles that</p> <p>15 you've written, at least since 1990, have all focused</p> <p>16 on some aspect of refractive surgery; is that correct?</p> <p>17 A. Most, yes.</p> <p>18 Q. Are there any since 1990 that haven't?</p> <p>19 A. I don't remember the years. I've written a few</p> <p>20 articles, one on swelling of the optic nerve after a</p> <p>21 disease called pseudotumor, another one about blindness</p> <p>22 in an individual from essential retinal artery</p> <p>23 occlusion in the optic -- in the retina, but --</p> <p>24 Q. Okay. And where are those articles? I'm</p> <p>25 sorry.</p> | <p style="text-align: right;">12</p> <p>1 inhibitors?</p> <p>2 A. No.</p> <p>3 Q. Have you lectured on any -- any PDE-5</p> <p>4 inhibitors?</p> <p>5 A. No.</p> <p>6 Q. You told me that you still have some general</p> <p>7 ophthalmology practice. What does that involve?</p> <p>8 A. Well, for -- from the time that I went into</p> <p>9 practice after I came back from fellowship, I have</p> <p>10 maintained and still see many of my general</p> <p>11 ophthalmology practices.</p> <p>12 My partner, who formed my practice, was the</p> <p>13 only neuroophthalmologist in the Twin Cities at the</p> <p>14 time, Dr. Irving Shapiro. He founded the Phillips Eye</p> <p>15 Institute. And he had a huge neuroophthalmology</p> <p>16 practice.</p> <p>17 He also made it his business to leave in the</p> <p>18 summer for eight weeks, and I used to see all of his</p> <p>19 patients. And I've continued to see some of them ever</p> <p>20 since.</p> <p>21 And I would say about a third of my time is</p> <p>22 still spent in general ophthalmology. I -- I enjoy</p> <p>23 seeing my patients, and I don't really want to give</p> <p>24 them up just because they don't fit into this</p> <p>25 particular pigeonhole.</p> |
| <p style="text-align: right;">11</p> <p>1 A. I think they're earlier in my CV. The</p> <p>2 pseudotumor article was written for Journal of the</p> <p>3 American Medical Association. No. 16, who I wrote with</p> <p>4 Dr. Deznick, who is head of Genetics at Mount Sinai in</p> <p>5 New York. No. 17 was related to that. And the</p> <p>6 pseudotumor article I think was around the same year.</p> <p>7 But they were before 1990, you're correct.</p> <p>8 Q. Okay. And the articles on central retinal</p> <p>9 artery occlusion was from '78 and '79?</p> <p>10 A. That's right.</p> <p>11 Q. Okay. And the book chapters that you've</p> <p>12 authored, those also relate to laser surgery; correct?</p> <p>13 A. That's right.</p> <p>14 Q. And the lectures that you've given, those have</p> <p>15 predominantly related to laser surgery; correct?</p> <p>16 A. Most. I also do some lectures on teaching</p> <p>17 physicians on medicolegal issues relating mostly to</p> <p>18 refractive surgery. But they're general to any</p> <p>19 practice -- anything in the practice of medicine.</p> <p>20 Q. Have you published any articles on ischemic</p> <p>21 optic neuropathy?</p> <p>22 A. No.</p> <p>23 Q. Have you lectured on ischemic optic neuropathy?</p> <p>24 A. No.</p> <p>25 Q. Have you written any articles on PDE-5</p> | <p style="text-align: right;">13</p> <p>1 Q. And within your general ophthalmology practice,</p> <p>2 do you diagnose patients with ischemic optic</p> <p>3 neuropathy?</p> <p>4 A. Yes.</p> <p>5 Q. And do you treat them?</p> <p>6 A. Unfortunately, that's why I like cornea. There</p> <p>7 isn't any good treatment, for the most part. You give</p> <p>8 them steroids, and they still lose their vision. I</p> <p>9 try.</p> <p>10 Q. And do you follow them or do you refer them to</p> <p>11 a neuroophthalmologist?</p> <p>12 A. I have a neuroophthalmologist in my practice.</p> <p>13 And -- and her name is Dr. Rubinfeld. And she's a M.D.</p> <p>14 Ph.D. Unfortunately, at age 46, she had a very bad</p> <p>15 stroke and -- and was out for two years. And myself</p> <p>16 and several of my partners ended up seeing many of her</p> <p>17 patients, as well.</p> <p>18 So I did follow them. Frustrating, because</p> <p>19 most of them don't get better.</p> <p>20 Q. And today in your practice, do you continue to</p> <p>21 follow those patients, or do you refer them to a</p> <p>22 neuroophthalmologist?</p> <p>23 A. I refer them back to Dr. Rubinfeld, who has,</p> <p>24 fortunately, made a good recovery. I -- I see some.</p> <p>25 Just to clarify, when someone loses their vision and</p> |

4 (Pages 10 to 13)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|---|--|
| <p style="text-align: right;">14</p> <p>1 they have optic atrophy, you say, "Come back in a 2 year." There -- there isn't anything, unfortunately, 3 to -- to do terrifically at this time that I can think 4 of for them. 5 Q. And when you see patients with ischemic optic 6 neuropathy, do you attempt to ascertain the cause of 7 that ischemic optic neuropathy? 8 A. Yes. We would work them up and rule out the 9 appropriate causes, particularly the treatable causes. 10 Q. Walk me through the steps that you would go 11 through with a patient who came in with ischemic optic 12 neuropathy. 13 A. The types of typical history one would do on a 14 patient when you lost your vision, how, what were you 15 doing, what you see, what you don't see, the things 16 that all ophthalmologists would ask their patient. And 17 then inquire into their medical health, the medications 18 they're taking, and any other symptoms of some of the 19 related diseases such as temporal arteritis that might 20 cause the disease. 21 Q. Anything else that you would do for the 22 patient? 23 A. Within that, I would probably at that time send 24 them to their internist, possibly a neurologist, and 25 possibly consult with the neuroophthalmologist within</p> | <p style="text-align: right;">16</p> <p>1 Q. And you know sildenafil is the brand -- the 2 generic name for Viagra; correct? 3 A. Yes, ma'am. 4 Q. Okay. Have you conducted any studies on blood 5 flow to the optic nerve? 6 A. No. 7 Q. Do you teach? 8 A. I do. 9 Q. And where do you teach? 10 A. At the University of Minnesota School of 11 Medicine. I am an adjunct full professor. That means I 12 teach and I don't get paid. I also have taught around 13 the country various ophthalmologists and various 14 courses, particularly relating to refractive surgery. 15 Q. And at the University of Minnesota, is there a 16 particular course that you teach? 17 A. No. The -- What I like to do now is have the 18 third-year medical students come over. I give them a 19 lecture, and they watch me in surgery. And sometimes 20 they come to my office and shadow me, I guess is the 21 right term. 22 Q. And the subject matter of the lecture is 23 refractive surgery? 24 A. It is. 25 Q. Now you're not an expert in hypertension, are</p> |
| <p style="text-align: right;">15</p> <p>1 my practice or occasionally elsewhere. 2 Q. And what would be the purpose of referring them 3 to their internist? 4 A. To make sure that there is -- that their entire 5 health is checked and that they don't have terrible 6 high blood pressure or temporal arteritis. 7 Q. And what would be the purpose of sending them 8 to a neurologist? 9 A. If there were associated neurologic findings or 10 there was some concern, I would send them to a 11 neurologist. Not always. Just -- It just depended on 12 the feel of the case. 13 Q. I asked you if you've published any articles on 14 ischemic optic neuropathy, and you told me no. But 15 have you conducted any studies on ischemic optic 16 neuropathy? 17 A. No. My office was part -- I know Dr. Rubinfeld 18 was part of the decompression trial, the -- for 19 ischemic optic neuropathy, but I -- I was not involved 20 with it. She was -- I -- I can't remember if she was 21 part of from the University of Minnesota or not. 22 She -- she teaches there, as well. 23 Q. Okay. And have you conducted any studies on -- 24 on sildenafil? 25 A. No.</p> | <p style="text-align: right;">17</p> <p>1 you? 2 A. No. 3 Q. Are you -- 4 A. Except I have it. So -- 5 MR. HOPPER: Right now. 6 THE WITNESS: And I've tried -- No, I -- I've 7 tried a number of medicines. It sort of makes me my 8 own personal expert. 9 BY MS. LESKIN: 10 Q. But you don't treat patients with hypertension 11 in your practice? 12 A. I do take their blood pressure if I'm 13 suspicious. We have a cuff, and we monitor it 14 sometimes, because patients -- Sometimes I'm the only 15 doctor people see. And we will try to send them to 16 their primary care doctor if -- if it's warranted. 17 Q. Do you prescribe medications to your patients 18 with hypertension for their hypertension? 19 A. Once in a while. Usually, they say, "I ran out 20 of my lisinopril, and can you write a prescription?" 21 And I know they're on it. I will prescribe it. I 22 usually try to not interfere with the primary care 23 doctors, because too many chefs ruin the stew. 24 Q. And you're not an expert in urology, are you? 25 Urology?</p> |

5 (Pages 14 to 17)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|--|--|
| <p style="text-align: right;">18</p> <p>1 A. No.</p> <p>2 Q. U-R-O. And you don't treat erectile</p> <p>3 dysfunction in your patients; correct?</p> <p>4 A. No.</p> <p>5 Q. Have you ever written a prescription for an</p> <p>6 erectile -- erectile dysfunction medication?</p> <p>7 A. No.</p> <p>8 Q. Are you an expert in epidemiology?</p> <p>9 A. I have an interest in epidemiology. I'm not an</p> <p>10 expert. I've spent some time looking, doing some -- I</p> <p>11 spent some time at the Center For Disease Control. I</p> <p>12 did some investigations of epidemics then. And I have</p> <p>13 been interested, but I am not an expert.</p> <p>14 Q. And you're not an endocrinologist; correct?</p> <p>15 A. No.</p> <p>16 Q. And do you diagnosis diabetes in your patients?</p> <p>17 A. Sometimes. Sometimes it presents with the eye</p> <p>18 findings first.</p> <p>19 Q. So they come in with diabetic retinopathy --</p> <p>20 retinopathy or some similar disease?</p> <p>21 A. Yes, or just sometimes people say, "I'm thirsty</p> <p>22 all the time, and I've gained weight, or I've lost</p> <p>23 weight," or --</p> <p>24 Q. And do you --</p> <p>25 A. -- you know -- we diagnose.</p> | <p style="text-align: right;">20</p> <p>1 A. Sure.</p> <p>2 Q. Is this my copy of the disk?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. We'll take a look at that at a break.</p> <p>5 MR. BECNEL: Dr. Sher, do you have more than</p> <p>6 one copy of that or just that one copy?</p> <p>7 THE WITNESS: I don't.</p> <p>8 MR. BECNEL: Okay. Then I can get some made.</p> <p>9 THE WITNESS: Thank you, sir.</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. You -- you also have an index to this disk. Is</p> <p>12 that what that is?</p> <p>13 A. I don't, but this is --</p> <p>14 MR. HOPPER: We can make you a copy of this,</p> <p>15 Lori.</p> <p>16 MS. LESKIN: May I see it?</p> <p>17 MR. HOPPER: Sure.</p> <p>18 MS. LESKIN: Can we mark this as an exhibit?</p> <p>19 MR. HOPPER: It's fine with me.</p> <p>20 MS. LESKIN: Is that okay?</p> <p>21 MR. BECNEL: Do you want me to copy it before?</p> <p>22 THE WITNESS: I -- I think that's just a</p> <p>23 printout of what -- I gave Mr. Hopper a copy of the</p> <p>24 CD.</p> <p>25 MR. HOPPER: Yeah. It's just a hard copy</p> |
| <p style="text-align: right;">19</p> <p>1 Q. And do you treat those patients, or do you</p> <p>2 refer them to someone else?</p> <p>3 A. I refer them, Ms. Leskin.</p> <p>4 Q. Now I know you've brought a disk with you</p> <p>5 today. Was that in response to the subpoena that was</p> <p>6 served?</p> <p>7 A. It is.</p> <p>8 Q. Okay. And can you tell us what's on that disk?</p> <p>9 A. I tried to provide everything that was</p> <p>10 requested in the -- in the subpoena. There's some</p> <p>11 billing records, CV, some e-mails, copies of the</p> <p>12 articles, most of which I was provided -- all of which</p> <p>13 I was provided and some of which I have reviewed. Is</p> <p>14 this a printout of it?</p> <p>15 MR. HOPPER: Mmm-hmm.</p> <p>16 THE WITNESS: I'm sorry. The various expert</p> <p>17 reports and a copy of my exam. And I -- retainer</p> <p>18 agreements.</p> <p>19 I also found one correspondence with Mr. Becnel</p> <p>20 that was not in that file because it was a separate</p> <p>21 file that I didn't -- couldn't find the electronic</p> <p>22 copy when -- at the time I made this, and I found it</p> <p>23 subsequently, and you're welcome to have.</p> <p>24 BY MS. LESKIN:</p> <p>25 Q. Okay. Can I --</p> | <p style="text-align: right;">21</p> <p>1 version of a -- that could serve as an index.</p> <p>2 MR. OVERHOLTZ: So that's our list of what's on</p> <p>3 the disk.</p> <p>4 THE WITNESS: Yeah.</p> <p>5 MS. LESKIN: Okay.</p> <p>6 MR. OVERHOLTZ: It's not his list. It's our</p> <p>7 list.</p> <p>8 MR. HOPPER: Yeah.</p> <p>9 THE WITNESS: Yeah.</p> <p>10 MS. LESKIN: Okay. Well, with that</p> <p>11 representation, is there an objection to marking it</p> <p>12 as an exhibit?</p> <p>13 MR. HOPPER: No. I don't have a problem.</p> <p>14 THE WITNESS: And --</p> <p>15 MS. LESKIN: Okay. So we're going to mark this</p> <p>16 as Exhibit 2.</p> <p>17 THE WITNESS: And I do it on a Mac, but I'm</p> <p>18 pretty sure you can -- I only use MacIntosh.</p> <p>19 MR. HOPPER: But just so you know, we ought to</p> <p>20 make extra copies of both of those because --</p> <p>21 MS. LESKIN: That's fine. And can we mark this</p> <p>22 e-mail as an exhibit, as well?</p> <p>23 MR. OVERHOLTZ: Let's make a copy of that one</p> <p>24 first before we put a sticker on it.</p> <p>25 MS. LESKIN: Okay. That's fine.</p> |

6 (Pages 18 to 21)

| | |
|---|--|
| <p style="text-align: right;">22</p> <p>1 MR. HOPPER: Do you want to just copy that,</p> <p>2 too?</p> <p>3 MS. LESKIN: Sure. Might as well.</p> <p>4 MR. HOPPER: All right.</p> <p>5 (Sher Exhibit No. 2, five-page document</p> <p>6 entitled Contents of CD labeled: Material Requested</p> <p>7 for Viagra NAION Depo, was marked for</p> <p>8 identification.)</p> <p>9 BY MS. LESKIN:</p> <p>10 Q. And just for the record, we've marked as</p> <p>11 Exhibit 2 a copy of the index that was prepared by</p> <p>12 counsel, and that purports to be the index of materials</p> <p>13 on the disk that was provided by Dr. Sher.</p> <p>14 A. I hope a disk was acceptable, because I was</p> <p>15 carrying too --</p> <p>16 Q. Oh --</p> <p>17 A. -- much clothing for the wedding I'm coming</p> <p>18 for.</p> <p>19 Q. That's -- that's fine.</p> <p>20 A. It's black tie.</p> <p>21 Q. Is -- You said that you use a Mac. Is this</p> <p>22 compatible only with a Mac?</p> <p>23 A. No.</p> <p>24 Q. Okay.</p> <p>25 A. It's -- it's -- it's --</p> | <p style="text-align: right;">24</p> <p>1 have another copy, that's fine, as well.</p> <p>2 I want to direct your attention first to the</p> <p>3 papers at the back of this. The last five or so pages</p> <p>4 is a listing entitled Legal Consulting?</p> <p>5 A. Yes.</p> <p>6 Q. Are there any updates to this list since it was</p> <p>7 provided to us that you know of?</p> <p>8 A. There are, and they are on the disk that I</p> <p>9 gave -- have given you.</p> <p>10 Q. Okay.</p> <p>11 A. Several -- several other things.</p> <p>12 Q. Okay. And have you worked with -- well, let's</p> <p>13 start with Mr. Overholtz. Have you worked with Mr.</p> <p>14 Overholtz before or his firm?</p> <p>15 A. I don't believe I have other than on this. I'm</p> <p>16 not sure. I've been involved with some exposures to</p> <p>17 massive spills of chlorine and ammonia, and there were</p> <p>18 a lot of law firms involved, and --</p> <p>19 MR. OVERHOLTZ: Not me.</p> <p>20 THE WITNESS: I don't know if Mr. Overholtz was</p> <p>21 involved.</p> <p>22 MR. OVERHOLTZ: It wasn't me.</p> <p>23 MS. LESKIN: Okay.</p> <p>24 THE WITNESS: I don't think so.</p> <p>25 BY MS. LESKIN:</p> |
| <p style="text-align: right;">23</p> <p>1 Q. It will be compatible with my regular old IBM?</p> <p>2 A. It -- it -- it should.</p> <p>3 Q. Okay.</p> <p>4 (A discussion was held off the record.)</p> <p>5 (Sher Exhibit No. 3, 13-page document entitled</p> <p>6 Expert Report of Neal A. Sher, M.D., FACS, was</p> <p>7 marked for identification.)</p> <p>8 BY MS. LESKIN:</p> <p>9 Q. I'm going to hand you what we have marked as</p> <p>10 Exhibit 3, which is a copy of the expert report we</p> <p>11 received in this case.</p> <p>12 MR. BECNEL: That's for both, Lori?</p> <p>13 MS. LESKIN: Well, that's what I'm looking. I</p> <p>14 think this is the --</p> <p>15 MR. HOPPER: This is Stanley.</p> <p>16 MS. LESKIN: No, they're both here -- followed</p> <p>17 by Martin.</p> <p>18 THE WITNESS: Yes.</p> <p>19 MR. HOPPER: All right. Yeah, it is.</p> <p>20 MS. LESKIN: Right? Both of them are here?</p> <p>21 MR. HOPPER: Yeah, they're here.</p> <p>22 MS. LESKIN: Okay.</p> <p>23 MR. HOPPER: That's right.</p> <p>24 BY MS. LESKIN:</p> <p>25 Q. You can keep ahold of the copy of that. If you</p> | <p style="text-align: right;">25</p> <p>1 Q. And how about Mr. Hopper? Have you worked with</p> <p>2 Mr. Hopper before?</p> <p>3 A. Yes. We have worked on the litigation</p> <p>4 involving these particular gas exposure, and people's</p> <p>5 eyes were injured among other body parts.</p> <p>6 Q. Is that listed under 2007 DPC litigation,</p> <p>7 chlorine spill?</p> <p>8 A. Yes. Yes, it is.</p> <p>9 Q. And then in 2006, Zimmerman Reed is also listed</p> <p>10 for Johnson, Clott versus CP Railway?</p> <p>11 A. Yeah. That's -- was related to CP Railroad's</p> <p>12 overturning tank cars and leaking tank cars.</p> <p>13 MR. BECNEL: The Minot case.</p> <p>14 THE WITNESS: Minot, North Dakota.</p> <p>15 BY MS. LESKIN:</p> <p>16 Q. And is that also the case for the Klier versus</p> <p>17 CP Railroad listed on the next page?</p> <p>18 A. Yes, ma'am. There -- there were a lot of</p> <p>19 people injured and a lot of plaintiffs.</p> <p>20 Q. Have you worked with Mr. Hopper or his firm on</p> <p>21 any other type of litigation other than the CP Railway?</p> <p>22 A. I don't think so, no.</p> <p>23 Q. How about Mr. Becnel? Have you worked with Mr.</p> <p>24 Becnel before?</p> <p>25 A. I -- I have on the same matters.</p> |

7 (Pages 22 to 25)

| | |
|---|--|
| <p style="text-align: right;">26</p> <p>1 Q. Okay.</p> <p>2 A. And -- and another matter.</p> <p>3 Q. What other matter?</p> <p>4 A. It has to do with infections from contam --</p> <p>5 from contact lens solutions.</p> <p>6 Q. Is that the Bausch & Lomb litigation?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Okay.</p> <p>9 MR. BECNEL: Lori, just to make the record</p> <p>10 complete. He might not know it. Zimmerman Reed,</p> <p>11 not Randy, but his partner or his retired partner</p> <p>12 starting January 1st were in the DCP case in -- in</p> <p>13 both Arizona and the DCP case in St. Louis, which</p> <p>14 were two separate -- One was a chlorine spill, and</p> <p>15 another one was an anhydrous ammonia spill.</p> <p>16 MS. LESKIN: Okay.</p> <p>17 MR. BECNEL: And I think that's it.</p> <p>18 MS. LESKIN: Thank you for the clarification.</p> <p>19 MR. BECNEL: But Randy I don't think worked on</p> <p>20 but one of those.</p> <p>21 MS. LESKIN: Let's mark a copy. He can keep</p> <p>22 the original --</p> <p>23 MR BECNEL: Okay.</p> <p>24 MS. LESKIN: -- and I will mark a copy of the</p> <p>25 e-mail. So we're going to mark as Exhibit 4 a copy</p> | <p style="text-align: right;">28</p> <p>1 MS. LESKIN: I have been in that situation</p> <p>2 myself.</p> <p>3 MR. HOPPER: You didn't do the draw that</p> <p>4 President Clinton got, huh?</p> <p>5 THE WITNESS: No, he -- the President -- the</p> <p>6 President got a much bigger crowd.</p> <p>7 (A discussion was held off the record.)</p> <p>8 BY MS. LESKIN:</p> <p>9 Q. Okay. Going back to what we've marked as</p> <p>10 Exhibit 4, which is the e-mail you provided us from you</p> <p>11 to Mr. Becnel, this e-mail is dated May 27th, 2005;</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. How long before the date of this e-mail did you</p> <p>15 have your first contact with anyone regarding the</p> <p>16 Viagra litigation?</p> <p>17 A. I believe this was the first contact.</p> <p>18 Q. I assume they called you in advance of your</p> <p>19 writing this e-mail?</p> <p>20 A. It was a phone call dated -- it was probably --</p> <p>21 I'm sort of obsessive when it comes to returning</p> <p>22 e-mails and phone calls, so I probably wrote the letter</p> <p>23 the same day that I received the phone call.</p> <p>24 Q. So when you wrote, "I appreciate your phone</p> <p>25 call today," that was the first contact you had with</p> |
| <p style="text-align: right;">27</p> <p>1 of the e-mail between you and Mr. Becnel that you</p> <p>2 provided to us. And Exhibit 2 is the index which I</p> <p>3 now don't have a copy of.</p> <p>4 (Sher Exhibit No. 4, two-page document, and</p> <p>5 e-mail from Neal A. Sher to Daniel Becnel dated May</p> <p>6 27, 2005, Subject: Visual loss, CV and fee</p> <p>7 schedule, was marked for identification.)</p> <p>8 MR. BECNEL: And I believe, Lori, I wanted to</p> <p>9 make the record complete. I had Dr. Sher, I think</p> <p>10 it was Mass Torts Made Perfect in Las Vegas I had</p> <p>11 him speak; is that correct?</p> <p>12 THE WITNESS: Yes.</p> <p>13 THE COURT REPORTER: I'm sorry. You said what?</p> <p>14 What -- Mass Torts in Las Vegas?</p> <p>15 MR. BECNEL: Mass Torts Made Perfect in Las</p> <p>16 Vegas. I had him lecture about a thousand lawyers</p> <p>17 that attended that.</p> <p>18 THE COURT REPORTER: Thank you.</p> <p>19 BY MS. LESKIN:</p> <p>20 Q. What was the subject matter of that lecture,</p> <p>21 Mr. Sher?</p> <p>22 A. It -- it had to do with the contact lens</p> <p>23 solution and ReNu and infections. There may have been</p> <p>24 a thousand lawyers at the meeting, but there were much</p> <p>25 fewer at the lecture.</p> | <p style="text-align: right;">29</p> <p>1 Mr. Becnel?</p> <p>2 A. That's right.</p> <p>3 Q. Okay. And you hadn't spoken with anyone about</p> <p>4 the Viagra litigation before that date?</p> <p>5 A. I had not.</p> <p>6 Q. Okay. What information was provided to you by</p> <p>7 Mr. Becnel during the phone call on May 27th, 2005?</p> <p>8 A. He brought to my attention, which I had</p> <p>9 heard -- I don't remember if it was in the media or not</p> <p>10 at that time, but -- and I was aware of Dr. Pomeranz's</p> <p>11 and Dr. Bhavsar's article. Because I know Dr. Bhavsar,</p> <p>12 and I knew Dr. Pomeranz. And it was a brief</p> <p>13 conversation indicating these cases and what I thought</p> <p>14 and would I look into it and -- and get back to you.</p> <p>15 Q. Did Mr. Becnel provide you with any information</p> <p>16 regarding any specific plaintiff?</p> <p>17 A. No. Not at that time.</p> <p>18 Q. And didn't provide you with any medical records</p> <p>19 for anyone?</p> <p>20 A. No.</p> <p>21 Q. In response to the phone call from Mr. Becnel,</p> <p>22 did you do any additional research --</p> <p>23 A. I did.</p> <p>24 Q. -- back in May of 2005?</p> <p>25 A. Yes.</p> |

8 (Pages 26 to 29)

| | |
|---|---|
| <p style="text-align: right;">30</p> <p>1 Q. And how much time did you spend doing that</p> <p>2 research?</p> <p>3 A. Probably three, four hours. I -- I -- I don't</p> <p>4 remember. But looking at the -- looking at the</p> <p>5 literature and doing some reading, maybe -- maybe</p> <p>6 somewhat more. I don't think I billed my time as much,</p> <p>7 but I just did try to find as much as I can and get</p> <p>8 back to him in a timely manner.</p> <p>9 Q. Do you -- do you have a list of the articles</p> <p>10 that you reviewed to help you prepare this e-mail?</p> <p>11 A. I do not. Eventually, the list is the material</p> <p>12 that's in -- in Exhibit 2. But at that time, I -- I</p> <p>13 didn't keep a record of what I've reviewed. There were</p> <p>14 several -- certainly the Pomeranz case report and</p> <p>15 articles. And I reviewed some of the writings on</p> <p>16 Professor -- Dr. Hayreh who was somewhat of a legend.</p> <p>17 And I remember him lecturing. He would come up to</p> <p>18 Minnesota, and he was quite colorful.</p> <p>19 Q. Did you discuss the issue with -- with anyone</p> <p>20 at the time other than the lawyers? Did you discuss</p> <p>21 the issue with anyone else in preparation of this</p> <p>22 e-mail?</p> <p>23 A. I did not.</p> <p>24 Q. So you didn't consult with any of your partners</p> <p>25 or with Dr. Bhavsar?</p> | <p style="text-align: right;">32</p> <p>1 didn't print everything out. I'm sorry.</p> <p>2 Q. But that will be on the disk you gave us?</p> <p>3 A. It will be.</p> <p>4 Q. So maybe during a break we can look at that --</p> <p>5 A. Sure.</p> <p>6 Q. -- and talk about that a little bit later some</p> <p>7 more.</p> <p>8 MR. BECNEL: Lori, just to make the record</p> <p>9 complete, I think I had dinner with Dr. Sher once</p> <p>10 with Mr. Arsenal while we were there on either the</p> <p>11 Medtronics or the Guidant case, and --</p> <p>12 THE WITNESS: We really didn't discuss --</p> <p>13 MR. BECNEL: We really didn't discuss this</p> <p>14 case. I just ...</p> <p>15 MS. LESKIN: That's fine.</p> <p>16 BY MS. LESKIN:</p> <p>17 Q. You indicated earlier that there was a list of</p> <p>18 literature on this disk that you provided us. And I</p> <p>19 assume looking at Num -- Exhibit 2, that's the</p> <p>20 materials under No. 6?</p> <p>21 A. I'm sorry. Do I have -- what I did with that</p> <p>22 thing --</p> <p>23 MS. LESKIN: Randy had it.</p> <p>24 MR. HOPPER: I grabbed the wrong one. Sorry.</p> <p>25 THE WITNESS: Yes.</p> |
| <p style="text-align: right;">31</p> <p>1 A. I did not.</p> <p>2 Q. After May 27th, 2005, when was the next time</p> <p>3 you spoke with anyone representing plaintiffs in this</p> <p>4 litigation?</p> <p>5 A. I don't recall the exact -- I -- I think there</p> <p>6 was a request -- I probably had a phone call with Mr.</p> <p>7 Becnel. He wanted me to -- you know -- stay involved.</p> <p>8 He asked me a few questions about my report.</p> <p>9 I believe I requested a retainer, \$2,500 to --</p> <p>10 for some of the time and future time, and I believe</p> <p>11 that the next contact I had involved Mr. Hopper and Mr.</p> <p>12 Hopper's firm. But I would have to go back to the</p> <p>13 billing records, which I didn't print out when that</p> <p>14 was. That would probably indicate the first, and I</p> <p>15 just don't remember it right now.</p> <p>16 Q. Can you tell me approximately, was it a year</p> <p>17 later? Was it three years later?</p> <p>18 A. If I recall, there was really nothing that</p> <p>19 happened for a while. Maybe -- maybe a year, but I'd</p> <p>20 be guessing. But I did give you a detailed log of my</p> <p>21 -- of my involvement with the case with the Zimmerman</p> <p>22 Reed firm. There really wasn't any further involvement</p> <p>23 pretty much with Mr. Becnel. I assumed they were</p> <p>24 working together and that Mr. Hopper was the contact</p> <p>25 point. And I just don't remember the date. I -- I</p> | <p style="text-align: right;">33</p> <p>1 BY MS. LESKIN:</p> <p>2 Q. Are there any other articles regarding the</p> <p>3 association between Viagra and NAION that you've</p> <p>4 reviewed?</p> <p>5 A. There -- I tried to look at all the case</p> <p>6 reports. I also looked through, and I tried to</p> <p>7 photocopy, but the thick -- the books were too thick,</p> <p>8 and I couldn't scan them. I have the Walsh & Hoyt, The</p> <p>9 Textbook of Neuro-Ophthalmology. It's about three or</p> <p>10 four volumes, and it's -- it's hard to photocopy.</p> <p>11 I've looked through the FDA websites as much as</p> <p>12 I can, and some of the labeling issues and some of the</p> <p>13 FDA correspondence. I believe that's here. There may</p> <p>14 be some other articles and case reports that I have</p> <p>15 reviewed that I did not necessarily have copies of to</p> <p>16 provide and quite a few that I've seen. But they've</p> <p>17 been referenced in -- in some of the materials handed</p> <p>18 to me, and I tried to look at as many as I can.</p> <p>19 Q. And the articles here listed under 6, the five</p> <p>20 articles that are listed here, are those articles that</p> <p>21 were provided to you or that you found on your own?</p> <p>22 A. Well, both. I -- I asked Mr. Hopper to provide</p> <p>23 me with any of the computer versions of articles that I</p> <p>24 can bring here. And I -- and I have other articles</p> <p>25 that I have brought. The one -- Dr. Levin's editorial,</p> |

9 (Pages 30 to 33)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|---|--|
| <p style="text-align: right;">34</p> <p>1 I -- I have other articles here. There was only a 2 limit to how much I could really carry. But I tried to 3 review as much as I can written about this particular 4 matter. 5 Q. Okay. When we've had a chance to look at the 6 disk, we'll come back to some of this. 7 A. Sure. 8 Q. Now looking again at your expert report, and 9 just because Stanley comes up first in the list here, 10 if I could ask you to look at the bottom of the second 11 page of Mr. Stan -- the report focused on Mr. Stanley. 12 A. Yes. 13 Q. You say that you based your opinion on your 14 clinical judgment gained from 28 years of practicing 15 ophthalmology and performing research and my review of 16 the pertinent literature. 17 A. That's right. 18 Q. The review of the pertinent literature, is that 19 what we just spoke about? 20 A. Yes. I -- I've tried to read and review in the 21 last two years as much that I can written about this 22 matter, related issues with a couple of the other 23 similar molecule drugs, the Levitra and Cialis, and -- 24 and NAION in general. 25 Q. And you said performing research. What</p> | <p style="text-align: right;">36</p> <p>1 make sure. 2 MR. BECNEL: The CDC is -- 3 BY MS. LESKIN: 4 Q. You haven't attempted to do any type of 5 epidemiological analysis on your own, have you? 6 A. No. 7 Q. Did you consult with anyone other than the -- 8 the attorneys about the -- about the issues in the 9 case? 10 MR. HOPPER: Objection; vague. 11 SPECIAL MASTER BORG: Overruled. 12 MR. HOPPER: Restate. 13 SPECIAL MASTER BORG: Do you understand the 14 question or are you able to answer it? 15 THE WITNESS: Can Ms. Leskin just be specific 16 as to what time, at what -- at what point. 17 BY MS. LESKIN: 18 Q. Sure. Well, you've already told me that in 19 connection with your May 2005 e-mail, you didn't 20 consult with anyone, any of your partners or 21 colleagues. 22 A. I did not. 23 Q. Okay. After that time, have you consulted with 24 any of your partners about the ischemic optic 25 neuropathy and Viagra issue?</p> |
| <p style="text-align: right;">35</p> <p>1 research did you perform? 2 A. In terms of research, researching this matter. 3 Q. And what research did you perform on this 4 matter? 5 A. The review of the documents that I have just 6 gone over with you, and review of the materials 7 provided to me. The other reports, the depositions, 8 the science, the other science that's out there that I 9 could ascertain. 10 Q. So the research was literature research? 11 A. It was. I didn't -- I didn't take a monkey and 12 tie off his posterior ciliary artery. 13 Q. Okay. That's what I wanted to make sure. 14 A. Yeah. Please. 15 Q. You didn't do any clinical research or animal 16 studies? 17 A. No. I -- I have spent enough time in the lab. 18 And I have been bitten by rats. I just try to avoid 19 them. 20 Q. Okay. 21 MR. HOPPER: You didn't assume, did -- did you? 22 MS. LESKIN: What was that? 23 MR. HOPPER: You didn't assume, did you, that 24 he did? 25 MS. LESKIN: No, I didn't. I just wanted to</p> | <p style="text-align: right;">37</p> <p>1 A. I discussed with Dr. Rubinfeld her thoughts in 2 terms of particularly Dr. Levin's editorial. And I'm 3 referring to the editorial in The Archives of 4 Ophthalmology in November of last year, if she thought 5 -- what she thought about the mechanism. And -- and in 6 general, I felt that these matters were confidential 7 and did not bring them up with other colleagues. 8 Q. You said you had a conversation with Dr. 9 Rubinfeld. When was that conversation? 10 A. I spoke to her approximately two, three days 11 ago in preparation to gather my thoughts on this matter 12 and asked her what she thought about Dr. Levin and his 13 work. 14 MR. HOPPER: Can we go off the record for just 15 a second? 16 MS. LESKIN: No, I want him to finish his 17 answer first. 18 MR. HOPPER: Well, I need to talk to you for 19 just a second about the -- 20 MS. LESKIN: Yeah, I need him to finish his 21 answer before we have that conversation. 22 MR. HOPPER: Well, I think he has. 23 MS. LESKIN: No, he was middle -- in the middle 24 of a sentence. 25 SPECIAL MASTER BORG: Okay. All right. Are</p> |

10 (Pages 34 to 37)

| | |
|--|--|
| <p style="text-align: right;">38</p> <p>1 you finished with your answer, Doctor?</p> <p>2 THE WITNESS: Yes.</p> <p>3 MS. LESKIN: Well, it said "Dr. Levin and" was</p> <p>4 the end of the sentence. So Can you finish that</p> <p>5 sentence, please?</p> <p>6 MR. HOPPER: I apologize. I didn't realize --</p> <p>7 THE WITNESS: I specifically engaged her in a</p> <p>8 conversation, because I was fascinated by Dr.</p> <p>9 Levin's pulling together the observations that I</p> <p>10 have noted and others, and I asked her what she</p> <p>11 thought about the editorial or the article. I don't</p> <p>12 know if it was an editorial or an article.</p> <p>13 MS. LESKIN: Okay. We can go off the record,</p> <p>14 and I would ask the witness to step out of the room.</p> <p>15 THE VIDEOGRAPHER: We are now going off the</p> <p>16 video record. The time is 9:09 a.m.</p> <p>17 (A discussion was held off the record.)</p> <p>18 MR. HOPPER: Let's go on the record. Ms.</p> <p>19 Leskin has just accurately represented the facts and</p> <p>20 the circumstances where both parties discovered that</p> <p>21 Dr. Sher's neuroophthalmologist partner had been</p> <p>22 contacted and consulted by each party. And so my</p> <p>23 concern is that she's going down a line of</p> <p>24 questioning now with respect to this, and I want to</p> <p>25 make sure we're clear before we get on the record</p> | <p style="text-align: right;">40</p> <p>1 Rubenfeld. I see this as a potential violation of</p> <p>2 the agreement, and I reserve the right to move to</p> <p>3 strike Dr. Sher on that basis.</p> <p>4 MR. HOPPER: As --</p> <p>5 MS. LESKIN: His last -- He just testified that</p> <p>6 he had a conversation two or three days ago, which</p> <p>7 is long after we entered into any agreement about</p> <p>8 Dr. Rubenfeld, and I'm going to investigate when the</p> <p>9 first conversation, how many conversations, what he</p> <p>10 spoke about with her. I don't intend to ask him</p> <p>11 whether he was aware that he wasn't permitted.</p> <p>12 That's not my concern. My concern is to know</p> <p>13 exactly what he talked about and when he talked</p> <p>14 about it with her.</p> <p>15 MR. HOPPER: Well --</p> <p>16 MR. OVERHOLTZ: Has Dr. Rubenfeld agreed to be</p> <p>17 your expert?</p> <p>18 MS. LESKIN: Dr. Rubenfeld met with us, agreed</p> <p>19 to be our expert, took money from us, and failed to</p> <p>20 mention that she was. And we have -- But we have an</p> <p>21 agreement between counsel in writing that neither</p> <p>22 side would hire her or that we would consult with</p> <p>23 her or anyone on our behalf.</p> <p>24 MR. BECNEL: All right --</p> <p>25 MS. LESKIN: That's what the agreement said.</p> |
| <p style="text-align: right;">39</p> <p>1 what the ground rules are about that so that the</p> <p>2 facts are accurately represented, because he doesn't</p> <p>3 necessarily know them. He was separate and</p> <p>4 completely out of those conversations.</p> <p>5 And so I want to be sure I'm on the same page</p> <p>6 with the Court and with Ms. Leskin about those</p> <p>7 ground rules, because I don't want her asking him a</p> <p>8 bunch of questions regarding this, because he was</p> <p>9 never consulted. He wasn't aware of it.</p> <p>10 What he's referring to at this point are</p> <p>11 conversations that he may have had with her prior to</p> <p>12 our even learning of this potential conflict. And</p> <p>13 so I need some assistance from the Court to make</p> <p>14 sure that these ground rules are set and that he --</p> <p>15 she's not asking him questions about something that</p> <p>16 he doesn't know about, and it's -- and that it's not</p> <p>17 in violation of the agreement that we've reached</p> <p>18 between the parties about Dr. Rosenfeld.</p> <p>19 MS. LESKIN: Well, if I can just respond.</p> <p>20 SPECIAL MASTER BORG: Sure.</p> <p>21 MS. LESKIN: The agreement that was reached</p> <p>22 between counsel is that neither side or anyone on</p> <p>23 their behalf would consult with Dr. Rubenfeld. I am</p> <p>24 reserving my right and I intend to go much further</p> <p>25 into these conversations that he had with Dr.</p> | <p style="text-align: right;">41</p> <p>1 MR. BECNEL: Lori -- This is Danny Becnel.</p> <p>2 First of all, I'm lead counsel in this case. You're</p> <p>3 supposed to make agreements through me. This is the</p> <p>4 first I have learned of either of these things. I</p> <p>5 retained Dr. Sher and anybody else that he thought</p> <p>6 was necessary.</p> <p>7 Now I didn't -- I've never talked to his</p> <p>8 partner. I didn't ask for any advice from his</p> <p>9 partner. I didn't direct him to ask for advice, but</p> <p>10 to contact me once I gave him a retainer.</p> <p>11 And the only thing I'm saying is Randy is</p> <p>12 liaison counsel, and you -- and he represents these</p> <p>13 two people. And so he can make whatever agreements</p> <p>14 he needs to on his clients, because Judge Magnuson,</p> <p>15 under the MDL rules, is required to only try cases</p> <p>16 before him with original jurisdiction in -- in his</p> <p>17 court. Any other, he's just doing pretrial</p> <p>18 discovery, et cetera, and then has to remand them</p> <p>19 under the Supreme Court edicts.</p> <p>20 So if you start filing those motions, I'm</p> <p>21 putting you on notice that you didn't make the</p> <p>22 proper investigation and it was done for litigation</p> <p>23 purposes to try to disqualify an expert that I had</p> <p>24 retained since 2005. And I'm sure -- and I don't</p> <p>25 even know what date you've talked to him about it.</p> |

11 (Pages 38 to 41)

| | |
|---|--|
| <p style="text-align: right;">42</p> <p>1 This is the first I hear about any of this.</p> <p>2 MS. LESKIN: I never talked with Dr. Sher</p> <p>3 before.</p> <p>4 MR. BECNEL: No, no, I'm talking about with</p> <p>5 his -- his firm. But I know I have told you that</p> <p>6 Dr. Sher was my expert.</p> <p>7 MS. LESKIN: And I never --</p> <p>8 MR. BECNEL: Judge --</p> <p>9 MS. LESKIN: -- contacted Dr. Sher. My -- my</p> <p>10 contact was with Dr. Rubinfeld. My agreement was</p> <p>11 with counsel for the plaintiffs who represented to</p> <p>12 me that he was able to make this agreement. He is</p> <p>13 counsel of record for these two plaintiffs --</p> <p>14 MR. BECNEL: I have no problem with --</p> <p>15 MS. LESKIN: -- in which Dr. Sher -- in which</p> <p>16 Dr. Sher has put in expert reports. The only cases</p> <p>17 that Dr. Sher has put in expert reports are these</p> <p>18 two cases, both of which are Zimmerman Reed cases.</p> <p>19 There's an agreement between me and Mr. Hopper</p> <p>20 that -- that absolutely precluded the conversation</p> <p>21 that -- that took place.</p> <p>22 SPECIAL MASTER BORG: Is that agreement in</p> <p>23 writing?</p> <p>24 MS. LESKIN: Yes.</p> <p>25 SPECIAL MASTER BORG: Okay.</p> | <p style="text-align: right;">44</p> <p>1 follow-up or anything else. And I want to be very</p> <p>2 clear. I don't want this stuff coming on to a</p> <p>3 record at this point until we figure out what those</p> <p>4 guidelines are.</p> <p>5 SPECIAL MASTER BORG: Well, let's -- let me --</p> <p>6 MS. LESKIN: Well, can I just respond with --</p> <p>7 with one additional point?</p> <p>8 SPECIAL MASTER BORG: Yes.</p> <p>9 MS. LESKIN: I'm sorry, Judge.</p> <p>10 Dr. Sher is not my witness. He is not my</p> <p>11 expert. I have never met him until today. I</p> <p>12 believe that plaintiff's counsel had an obligation</p> <p>13 to inform him not to talk to Dr. Rubinfeld in light</p> <p>14 of the agreement, knowing that they were partners,</p> <p>15 knowing the situation and how this came to be. So I</p> <p>16 do want to ask him if he was aware that he was not</p> <p>17 supposed to be consulting with Dr. Rubinfeld.</p> <p>18 SPECIAL MASTER BORG: Well, let's -- let's talk</p> <p>19 about ground rules.</p> <p>20 MR. OVERHOLTZ: Well, he -- he -- he laid out</p> <p>21 exactly what he asked her about. He asked her about</p> <p>22 an editorial --</p> <p>23 MS. LESKIN: Yeah.</p> <p>24 MR. OVERHOLTZ: -- that appeared in</p> <p>25 the publication of --</p> |
| <p style="text-align: right;">43</p> <p>1 MR. HOPPER: Yeah. And she's absolutely</p> <p>2 correct about that. We have a situation here where</p> <p>3 many, meaning several, right hands did not know what</p> <p>4 left hands were doing.</p> <p>5 SPECIAL MASTER BORG: Yeah.</p> <p>6 MR. HOPPER: And I'm -- I want to just be sure</p> <p>7 that the ground rules are set based upon this</p> <p>8 agreement. Because I don't think Dr. Sher is aware</p> <p>9 of or knew or knows, and he may go down the hall and</p> <p>10 talk to Dr. Rubinfeld about another patient. And in</p> <p>11 the course of that, because it might have something</p> <p>12 to do with ischemic neuropathy, because, as he</p> <p>13 testified, he deals with this issue and diagnoses</p> <p>14 it, and he may say to her, "What do you think about</p> <p>15 the Levin editorial?" It may have nothing to do</p> <p>16 with these clients. And I don't even know if he</p> <p>17 knows about the agreement that we struck here.</p> <p>18 SPECIAL MASTER BORG: Yeah.</p> <p>19 MR. HOPPER: And so -- so we've got to have</p> <p>20 some real clear guidelines on where this is gonna</p> <p>21 go, or it's going to prejudice not potentially just</p> <p>22 us on the claims side -- it could -- it could</p> <p>23 prejudice Pfizer here. So I think we've got to</p> <p>24 figure this out before anybody goes down any line of</p> <p>25 questioning either on the direct exam or any</p> | <p style="text-align: right;">45</p> <p>1 MS. LESKIN: And I didn't -- and I didn't ask</p> <p>2 to go any further --</p> <p>3 SPECIAL MASTER BORG: Whoa. Hey, just a minute</p> <p>4 here. What ground rules are you suggesting?</p> <p>5 MR. BECNEL: Num -- number one --</p> <p>6 MR. OVERHOLTZ: Not --</p> <p>7 MR. BECNEL: -- Daniel Becnel has learned about</p> <p>8 this right now.</p> <p>9 SPECIAL MASTER BORG: Well, we know that.</p> <p>10 You've already put that on the record. I want to</p> <p>11 know what the ground rules are so we can get on with</p> <p>12 this thing.</p> <p>13 MR. HOPPER: I think Lori -- I think Lori and I</p> <p>14 are in agreement, but I think we need to get clear</p> <p>15 on that. We did advise Dr. Sher of the</p> <p>16 circumstances that had occurred with his partner.</p> <p>17 SPECIAL MASTER BORG: You did?</p> <p>18 MR. HOPPER: I did.</p> <p>19 SPECIAL MASTER BORG: Okay.</p> <p>20 MR. HOPPER: Yes, I did. And if he had other</p> <p>21 conversations with her, I know nothing about that.</p> <p>22 SPECIAL MASTER BORG: So he was aware of your</p> <p>23 agreement with Pfizer's counsel -- Pfizer's -- Ms.</p> <p>24 Leskin?</p> <p>25 MR. HOPPER: He was aware of the fact that Dr.</p> |

12 (Pages 42 to 45)

| | |
|---|--|
| <p style="text-align: right;">46</p> <p>1 Rubinfeld would not be retained by either side.</p> <p>2 SPECIAL MASTER BORG: Okay. He didn't know you</p> <p>3 had an agreement that she wouldn't consult with</p> <p>4 anybody on this?</p> <p>5 MR. HOPPER: I don't know to what extent he</p> <p>6 didn't know of -- of a written agreement.</p> <p>7 SPECIAL MASTER BORG: Okay. Well, here's --</p> <p>8 MR. HOPPER: But he knew that Dr. Rubinfeld</p> <p>9 would not be working with the plaintiffs or with the</p> <p>10 defendants because of the -- of the misunderstanding</p> <p>11 apparently that Dr. Rubinfeld had. Because when she</p> <p>12 originally -- when we originally contacted her, she</p> <p>13 did not disclose to us that she had had any -- any</p> <p>14 conversations or --</p> <p>15 SPECIAL MASTER BORG: No -- no, I understand</p> <p>16 you've both got -- you've both got a little -- not</p> <p>17 intentionally, but blind-sided by her.</p> <p>18 MR. HOPPER: Yeah, yeah. Yeah, right.</p> <p>19 SPECIAL MASTER BORG: But it -- here's the --</p> <p>20 My question to you is what are the ground rules that</p> <p>21 are you suggesting?</p> <p>22 MR. HOPPER: I don't think -- I think it --</p> <p>23 potentially, there's potential prejudice for her to</p> <p>24 go down a line of inquiry with Dr. Sher about the</p> <p>25 circumstances that occurred with Dr. Rubinfeld</p> | <p style="text-align: right;">48</p> <p>1 think the agreement is in place particularly and</p> <p>2 specifically to keep this from happening.</p> <p>3 MS. LESKIN: The agreement is in place to keep</p> <p>4 him from having the conv -- the very conversation</p> <p>5 with Dr. Rubinfeld that he just said he had. He</p> <p>6 said that he spoke to Dr. Rubinfeld two or three</p> <p>7 days ago in preparation to gather his thoughts.</p> <p>8 That's for this deposition, this opinion that he's</p> <p>9 giving --</p> <p>10 MR. BECNEL: Well --</p> <p>11 MS. LESKIN: -- and let me finish.</p> <p>12 MR. BECNEL: Okay.</p> <p>13 MS. LESKIN: -- in this case. That's exactly</p> <p>14 what this agreement that I had with Mr. Hopper was</p> <p>15 designed to prevent. And there is no reason that I</p> <p>16 should be precluded from building my factual record</p> <p>17 to file a Motion To -- To Strike Dr. Sher's</p> <p>18 testimony.</p> <p>19 SPECIAL MASTER BORG: But -- Maybe. If that's</p> <p>20 what you choose to do.</p> <p>21 MS. LESKIN: If I choose to do it.</p> <p>22 MR. BECNEL: All right. Number one, I</p> <p>23 disclosed to Ms. Leskin years ago that Dr. Sher was</p> <p>24 my expert. She knew that. Purposefully, she sent</p> <p>25 somebody over there --</p> |
| <p style="text-align: right;">47</p> <p>1 over -- over here independent -- simply because</p> <p>2 they're in the same office.</p> <p>3 He consults with her on any number of issues</p> <p>4 and has conversations with her and on all kinds of</p> <p>5 patients and things of that nature. And for her to</p> <p>6 start questioning Dr. Sher about that when we had</p> <p>7 this side agreement in place I believe potentially</p> <p>8 is going to prejudice the plaintiffs in the matter.</p> <p>9 And I think actually it potentially could prejudice</p> <p>10 her own client. I think we've got to keep that out</p> <p>11 of this is what I feel.</p> <p>12 SPECIAL MASTER BORG: Out of this examination?</p> <p>13 MR. HOPPER: Yes.</p> <p>14 SPECIAL MASTER BORG: Well, then how and when</p> <p>15 does she make that examination?</p> <p>16 MR. HOPPER: It's -- it's -- There's no --</p> <p>17 there's nothing there to ... If she wants to deal</p> <p>18 -- if she believes somehow, for example -- I --</p> <p>19 I don't know what she thinks, by the way. I</p> <p>20 don't know where she's going with this.</p> <p>21 MS. LESKIN: I just told you.</p> <p>22 MR. HOPPER: But -- but I -- I know what the</p> <p>23 agreement was that we had, and now if she's going to</p> <p>24 try to open up Pandora's box on this and in my view</p> <p>25 start to violate the agreement, because she -- I</p> | <p style="text-align: right;">49</p> <p>1 MS. LESKIN: Oh, give me a break.</p> <p>2 MR. BECNEL: -- to see one of his partners,</p> <p>3 which is a violation of ethics rules.</p> <p>4 Secondly, she gave him a retainer to try to</p> <p>5 conflict him out, because I told him if we have to</p> <p>6 try a case in Minnesota, and sometimes MDL judges by</p> <p>7 stipulation will try a case from Texas or anywhere</p> <p>8 else by stipulation, but only by stipulation, that</p> <p>9 she's tried to conflict him out, knowing that we had</p> <p>10 him retained since 2005, and he would be our</p> <p>11 case-specific expert for whatever trials we needed</p> <p>12 in Minnesota, not anywhere else, per se. And as</p> <p>13 such, that she purposefully did not notify me of</p> <p>14 this as lead counsel. She purposely did not notify</p> <p>15 Mr. Hopper to notify me about this.</p> <p>16 And I'm the person that's responsible for this</p> <p>17 entire Plaintiffs' Committee in this case. And as</p> <p>18 such, by failure to do that, I could have pre --</p> <p>19 nipped that in the bud the day it happened. But I</p> <p>20 was kept in the dark. And I think this is a serious</p> <p>21 ethical violation.</p> <p>22 SPECIAL MASTER BORG: All right. We're -- you</p> <p>23 know what --</p> <p>24 MS. LESKIN: Judge Borg, I am seriously tired</p> <p>25 of my ethics being repeatedly questioned by Mr.</p> |

13 (Pages 46 to 49)

| | |
|--|---|
| <p style="text-align: right;">50</p> <p>1 Becnel. There is absolutely no evidence for 2 anything he just said. In fact, he doesn't even 3 know that Dr. Rubinfeld is a woman. I've never 4 spoken to Dr. Sher before today. I had no idea that 5 Dr. Rubinfeld was hired by you. She never told us 6 that. And I had conversations with Mr. Hopper. We 7 had cordial discussions about this. No one is 8 questioning anyone's ethics on this.</p> <p>9 MR. BECNEL: I'll file the necessary complaint.</p> <p>10 MS. LESKIN: And we reached an agreement. You 11 file a paper, and I'll file a Rule 11 motion against 12 you, because I am tired of you insulting my ethics.</p> <p>13 SPECIAL MASTER BORG: Okay. We're done. 14 That's it.</p> <p>15 The examination is going to continue. The 16 objections are overruled. I'm going to let her make 17 fair inquiry, and she gets to anyway, as to who she 18 consults -- he consults with in forming any 19 opinions.</p> <p>20 I think you would all agree that when and if a 21 motion of disqualification is brought, I think you 22 all agree it isn't going to be me who's going to 23 hear it; is that fair?</p> <p>24 MS. LESKIN: That's correct.</p> <p>25 MR. BECNEL: Judge --</p> | <p style="text-align: right;">52</p> <p>1 got ourselves set here, and I'm not going to put 2 anything else on the record with counsel out of 3 here. So let's take a five-minute break.</p> <p>4 (A short break was held from 9:24 a.m. to 9:43 5 a.m.)</p> <p>6 THE VIDEOGRAPHER: We are back on the video 7 record. The time is 9:43 a.m.</p> <p>8 BY MS. LESKIN:</p> <p>9 Q. Before the break, Doctor, we were discussing 10 your last conversation with Dr. Rubinfeld.</p> <p>11 A. Yes.</p> <p>12 Q. And just to be clear, you said you spoke with 13 her two to three days ago to get prepared for the 14 deposition?</p> <p>15 A. No.</p> <p>16 Q. Okay. What was the context in which you spoke 17 with Dr. Rubinfeld?</p> <p>18 A. It was on Tuesday, which is the only day that 19 she's in the same office I am and I see her. And her 20 office is down the hall from me. And between patients, 21 I have been trying to reach a Dr. Leonard Levin who 22 wrote the editorial I mentioned in The Archives. And I 23 asked her if she knew Dr. Levin, and she said she did. 24 And I asked if she -- he was in Montreal, because I was 25 looking in the Montreal phone directory, and she wasn't</p> |
| <p style="text-align: right;">51</p> <p>1 SPECIAL MASTER BORG: I mean I think your 2 trial -- I think your trial judge gets that.</p> <p>3 MR. OVERHOLTZ: Let's just make sure. Lori's 4 -- I mean -- you know -- as Randy said, Dr. Sher, if 5 he asked her about a study -- I mean -- I just want 6 to make sure that the nature of this examination 7 is -- you know -- fair and -- you know -- not 8 accusing him of violating some obligation that he 9 had or something like that.</p> <p>10 SPECIAL MASTER BORG: Well, we'll steer clear 11 of accusations. This is a deposition for evidence 12 and facts. And -- you know -- accusations -- If 13 that comes up in the inquiry, we'll deal with that 14 when it comes up, and you can make whatever 15 objections you think are appropriate.</p> <p>16 MR. BECNEL: And I would like to put on the 17 record that Ms. Leskin is representing a company who 18 has pled guilty.</p> <p>19 MS. LESKIN: Oh, goodness gracious.</p> <p>20 MR. BECNEL: But --</p> <p>21 MS. LESKIN: I'm taking a break.</p> <p>22 MR. BECNEL: You can take any breaks you want.</p> <p>23 SPECIAL MASTER BORG: You know what? Mr. 24 Becnel, that doesn't need to go on this record, so 25 I -- You know what? It's not going to go on. We've</p> | <p style="text-align: right;">53</p> <p>1 sure where he lived. And I said that he wrote this 2 article and she -- she had read it. And she said that 3 Dr. Levin had once been out here to speak in 4 Minneapolis a few years ago for the -- some type of a 5 conference. And that was the extent of the 6 conversation.</p> <p>7 I asked her about the article, what she 8 thought, and she really didn't give me an answer. But 9 that was the extent of the conversation.</p> <p>10 Q. Okay.</p> <p>11 A. And I found out later that Dr. Levin spends his 12 time in Madison, Wisconsin and Montreal, and that's why 13 I couldn't reach him.</p> <p>14 Q. Have you since spoken to Dr. Levin?</p> <p>15 A. I did.</p> <p>16 Q. Okay. And when did you speak to Dr. Levin?</p> <p>17 A. I spoke to Dr. Levin -- it would have been on 18 Wednesday night. I e-mailed him and asked him to call 19 me; I wanted to discuss his article. And he did. I 20 had never met him before.</p> <p>21 Q. Okay. We'll come back to that discussion.</p> <p>22 Have you had the opportunity to talk to Dr. Rubinfeld 23 at any other time regarding the association between 24 Viagra and NAION?</p> <p>25 A. Initially, I spoke to Dr. Rubinfeld asking her</p> |

14 (Pages 50 to 53)

| | |
|--|---|
| <p style="text-align: right;">54</p> <p>1 if she wanted to be involved with the litigation. I 2 can't remember when that was. Maybe four, five, six 3 months ago. And she -- as I had spoken to Mr. Hopper 4 and I'd said, "Can -- Did you want Dr. Rubinfeld 5 involved? She's a neuroophthalmologist." And she did 6 not -- and she didn't tell me at the time that she had 7 been involved with this litigation. If I had known, I 8 wouldn't have asked her. 9 And then it -- And she sometimes can get a 10 little confused. She's -- she's a very intense person 11 and very fast-talking New Yorker. But since her 12 stroke, sometimes there's been some issues. And then I 13 was informed that she was involved in some way with 14 another law firm, and I believe I wrote Randy or called 15 Randy and said that -- that she can't really be 16 involved; she's working for this. So I wouldn't have 17 asked her had I known. She didn't tell me. 18 Q. Okay. 19 A. And that was the last I really talked to her 20 about anything regarding the case. And I did not speak 21 to her regarding the case on Tuesday, only where I can 22 find Dr. Levin. 23 Q. Okay. And that was the extent of your 24 conversation, not to get her thoughts as to the 25 mechanism discussed in Dr. Levin's --</p> | <p style="text-align: right;">56</p> <p>1 Q. So if you do need to see it, I'm happy to show 2 you -- 3 A. Yeah. 4 Q. -- the screen -- 5 A. Thank you. 6 Q. -- and we could print up a copy at some point 7 if we need to. 8 MR. HOPPER: And I may want to have a look at 9 that, too. Just -- Is it possible that I can come 10 around there or -- 11 MS. LESKIN: You can come around here. I'm 12 okay with that. 13 MR. HOPPER: Well, I don't want to take you 14 away from what you need to look at. 15 MS. LESKIN: No. Yeah, I mean I'm happy to 16 share my computer, that's fine. 17 THE WITNESS: And that was two nights ago when 18 I made the disk -- three nights ago, uh-huh. 19 MS. LESKIN: Okay. 20 MR. HOPPER: I just -- 21 BY MS. LESKIN: 22 Q. The earliest date you have on the invoice that 23 I found, and if there's more than one, you can tell me, 24 but the only one that I found, the earliest date on 25 here is August 6th, 2008.</p> |
| <p style="text-align: right;">55</p> <p>1 A. That's -- 2 Q. I mean, in Dr. Levin's editorial? 3 A. Yeah, we didn't -- Unfortunately, we were both 4 seeing patients, so we really didn't talk. 5 Q. And is it fair to say that you have not sought 6 her opinion in reaching your own opinion? 7 A. That's correct. 8 Q. Okay. During the break, I was able to pull up 9 some of the billing records that you provided to us in 10 the litigation. 11 A. Mmm-hmm. 12 Q. And I tried to print them out, but -- 13 A. They didn't print? 14 Q. -- for some reason, I couldn't get the computer 15 to print them. So maybe I could do that during another 16 break. But I just wanted to ask you some questions. 17 I'll make some representations about what's on my 18 screen here. It really is just your spreadsheet -- 19 A. Yeah. 20 Q. -- as you can see. 21 A. Yes. 22 Q. And I've opened up in Excel. 23 A. Yeah. 24 Q. I haven't edited it in any way. 25 A. Great.</p> | <p style="text-align: right;">57</p> <p>1 MR. HOPPER: Excuse me one second. Could you 2 -- I'm sorry to interrupt. I -- I could enter a 3 formal objection, but all I'm trying to do is just 4 lay some foundation for what it is -- 5 MS. LESKIN: Sure. 6 MR. HOPPER: -- you're looking at. 7 MS. LESKIN: Sure. 8 MR. HOPPER: Because just to say "invoice" 9 doesn't -- 10 MS. LESKIN: Sure. Just to be clear, you 11 provided us with a disk this morning. 12 THE WITNESS: Yes. 13 BY MS. LESKIN: 14 Q. And one of the files on the disk, you 15 represented your billing records were on here. 16 A. Which you requested. 17 Q. Right. And that was in response to our 18 subpoena. And on the disk, there is a file entitled 19 "Sher invoices ZR Pfizer case" -- 20 A. Yeah. 21 Q. -- a folder. 22 A. Zimmerman Reed Pfizer. 23 Q. Okay. And, in fact, I'll even show you where I 24 started. This is the top -- 25 MR. HOPPER: And those are invoices that the</p> |

15 (Pages 54 to 57)

| | |
|--|---|
| <p style="text-align: right;">58</p> <p>1 doctor sent to my law firm.</p> <p>2 MS. LESKIN: Well, that's what I want to --</p> <p>3 what I'm trying to --</p> <p>4 MR. HOPPER: Okay. Okay. Okay.</p> <p>5 MS. LESKIN: So the first file that comes up is</p> <p>6 one called "Materials for Sher Deposition Martin</p> <p>7 Stanley Pfizer No. 2390"; right?</p> <p>8 THE WITNESS: That's correct. That's the whole</p> <p>9 folder.</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. That's the master folder?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And when I open that folder, there are</p> <p>14 several different files here; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And I went to this one called "ZR NAION</p> <p>17 Invoices."</p> <p>18 A. That's correct.</p> <p>19 Q. Okay. And that would be Zimmerman Reed NAION</p> <p>20 Invoices; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Now I notice there's also a separate one here</p> <p>23 that says "Sher Invoices ZR Pfizer Case" that seems to</p> <p>24 have the same files, but we can talk about that in a</p> <p>25 second if you --</p> | <p style="text-align: right;">60</p> <p>1 A. Yes.</p> <p>2 Q. -- there's four Word documents; correct?</p> <p>3 A. Right.</p> <p>4 Q. And then there's an Excel document?</p> <p>5 A. Correct.</p> <p>6 Q. Correct? And if I opened up that file, it's</p> <p>7 called "ZR Viagra NAION Work Log Copy No. C2D9?" And</p> <p>8 that's what's here is opened on my screen; correct?</p> <p>9 A. Yes, ma'am.</p> <p>10 MR. HOPPER: Well, for clarification purposes,</p> <p>11 it's not when the litigation started up again. It's</p> <p>12 when you --</p> <p>13 THE WITNESS: No, no. No, no. Just my</p> <p>14 involvement, yes.</p> <p>15 MR. HOPPER: Yes. Thank you.</p> <p>16 MS. LESKIN: Okay. So what I have on my screen</p> <p>17 is a read-only version of the invoice that -- the</p> <p>18 spreadsheet that you have provided us?</p> <p>19 THE WITNESS: Mmm-hmm.</p> <p>20 BY MS. LESKIN:</p> <p>21 Q. Does that look to be complete?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. So that the first date on here appears</p> <p>24 to be August 6th, 2008? And the --</p> <p>25 A. That's right.</p> |
| <p style="text-align: right;">59</p> <p>1 A. Yeah. Basically, I do this myself. It's not</p> <p>2 done through my office, the legal consulting, unless</p> <p>3 the -- When the patients are examined in my office,</p> <p>4 they're sent separate. And I'm not very good at</p> <p>5 spreadsheets. And I can do a simple spreadsheet. And</p> <p>6 that's how I do my legal --</p> <p>7 Q. Okay.</p> <p>8 A. -- legal work.</p> <p>9 Q. And they just ended up in two different folders</p> <p>10 somehow?</p> <p>11 A. I may have put --</p> <p>12 Q. That's fine.</p> <p>13 A. -- two of them in. And the -- what I would</p> <p>14 call the invoice would be the actual bill. And they're</p> <p>15 listed there. And I think I've enclosed them. They're</p> <p>16 probably on a Word document.</p> <p>17 Q. Right.</p> <p>18 A. And I keep the running log of my work in the</p> <p>19 case. And, as you mentioned, because I didn't remember</p> <p>20 the date, I guess the first time this case again</p> <p>21 started up was last summer --</p> <p>22 Q. Okay.</p> <p>23 A. -- in August of '08.</p> <p>24 Q. So let's just take a look. So if I open the</p> <p>25 folder that's entitled "ZR NAION Invoices" --</p> | <p style="text-align: right;">61</p> <p>1 Q. And the last date on here appears to be</p> <p>2 February 9th, 2008; correct?</p> <p>3 A. Correct.</p> <p>4 Q. So between August of 2008 and -- I'm sorry --</p> <p>5 Before August of 2008, did you have any communication</p> <p>6 with anyone from the Zimmerman Reed law firm?</p> <p>7 A. Regarding this matter?</p> <p>8 Q. Regarding this matter.</p> <p>9 A. I don't think so.</p> <p>10 Q. Okay. If you did have contact, would that</p> <p>11 appear on this spreadsheet?</p> <p>12 A. It should, because it would involve my being --</p> <p>13 probably wanting to bill them for my time.</p> <p>14 Q. Okay.</p> <p>15 A. So I hope I didn't forget hours.</p> <p>16 Q. And the initial contact that you had with Mr.</p> <p>17 Becnel in May of 2005, did you bill Mr. Becnel for</p> <p>18 that?</p> <p>19 A. He sent me a \$2,500 retainer. I don't believe</p> <p>20 I actually billed him, but --</p> <p>21 Q. Okay.</p> <p>22 A. -- he sent it.</p> <p>23 Q. And were there any other checks received or</p> <p>24 invoices sent with Mr. Becnel between May of 2005 and</p> <p>25 August of 2008?</p> |

16 (Pages 58 to 61)

| | |
|--|--|
| <p style="text-align: right;">62</p> <p>1 A. I think the answer is no.</p> <p>2 Q. Okay. And if there were such records, if there</p> <p>3 was such an invoice sent, where would you have a record</p> <p>4 of that?</p> <p>5 A. Probably be in my home computer. But I -- I</p> <p>6 don't believe that there's extra hours for Mr. Becnel.</p> <p>7 Everything switched over to the Zimmerman Reed firm,</p> <p>8 and I just keep that --</p> <p>9 Q. Okay.</p> <p>10 A. -- one log.</p> <p>11 Q. Now the reports that you provided to us are</p> <p>12 dated December 1, 2008 --</p> <p>13 A. Right.</p> <p>14 Q. -- for Mr. Stanley, and November 25th, 2008 for</p> <p>15 Mr. Martin; correct?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. And if you look on your invoice, you</p> <p>18 actually have an entry on December 1, 2008, says</p> <p>19 "Revised draft report discussion?"</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. And that refers to Mr. Stanley's report?</p> <p>22 A. Probably, yeah, if it says that.</p> <p>23 Q. Okay. And on November 25th, 2008, you have an</p> <p>24 entry that says, "Finish reports Mr. Martin and</p> <p>25 Stanley"; correct?</p> | <p style="text-align: right;">64</p> <p>1 A. No. There were separate bills. And I don't</p> <p>2 have them from Eye Care Associates. I could provide</p> <p>3 them, if you want --</p> <p>4 Q. Okay.</p> <p>5 A. -- my corporation that I'm -- that I'm a</p> <p>6 partner.</p> <p>7 Q. When you examined Mr. Martin and Mr. Stanley,</p> <p>8 were charts created at your office for them?</p> <p>9 A. Yes, they were.</p> <p>10 Q. They -- they were not patients at your -- at</p> <p>11 Eye Care prior to those visits; correct?</p> <p>12 A. No. They were not.</p> <p>13 Q. Okay. And do we have copies of their charts</p> <p>14 that were created for them on this disk?</p> <p>15 A. No. They were probably provided to you, and I</p> <p>16 have copies, the photocopies of the charts here. But</p> <p>17 that disk was in my home computer, and I don't scan</p> <p>18 records into the home computer.</p> <p>19 Q. Okay. So you have --</p> <p>20 A. But you -- you --</p> <p>21 Q. You said --</p> <p>22 A. -- I'm sure you have copies and I have copies.</p> <p>23 Q. I don't have copies from your files.</p> <p>24 A. I -- I do here. I --</p> <p>25 MR. HOPPER: Did you ask for them?</p> |
| <p style="text-align: right;">63</p> <p>1 A. Right. I was working on them together.</p> <p>2 Q. Okay. Now you mentioned something earlier, and</p> <p>3 I want to make sure I understood you. You said when</p> <p>4 you do an examination, that's billed through someone</p> <p>5 else?</p> <p>6 A. When patients are seen in my office, my office</p> <p>7 bills whoever the payer is for that examination. And</p> <p>8 in this case, the examination and the report.</p> <p>9 My agreement with my office is my legal</p> <p>10 consulting, when it does not involve, per se, patients</p> <p>11 seen in the office is -- is my own separate issue. And</p> <p>12 when the patients are seen, it generally is.</p> <p>13 Occasionally what comes up here is I start</p> <p>14 something a year or so before that has nothing to do</p> <p>15 with the office. Patients get seen in the office. It</p> <p>16 gets a little muddy. But my agreement is that that</p> <p>17 billing generally is my own practice's. It doesn't</p> <p>18 have much to do with my practice.</p> <p>19 Q. Okay.</p> <p>20 A. But I -- My practice billed for those</p> <p>21 examinations.</p> <p>22 Q. So on the report, where you say that Mr. Martin</p> <p>23 and Mr. Stanley were examined on September 4th, 2008,</p> <p>24 that -- the charge for that visit would not appear on</p> <p>25 the invoice that's currently up on my computer?</p> | <p style="text-align: right;">65</p> <p>1 MS. LESKIN: I believe we did. Off the record.</p> <p>2 Let's see here.</p> <p>3 THE WITNESS: But I do have them, if you need</p> <p>4 --</p> <p>5 MS. LESKIN: Okay.</p> <p>6 MR. HOPPER: Can you let me know when you did,</p> <p>7 when you asked for them? And I -- and by asking</p> <p>8 that, I'm certainly not implying --</p> <p>9 MS. LESKIN: Yeah.</p> <p>10 MR. HOPPER: -- that you didn't. I just don't</p> <p>11 recall it.</p> <p>12 MS. LESKIN: That's fine.</p> <p>13 THE WITNESS: I brought color copies. I</p> <p>14 assumed you would have them or would need them, so I</p> <p>15 have ...</p> <p>16 BY MS. LESKIN:</p> <p>17 Q. Then I'm going to mark this Exhibit 5, a copy</p> <p>18 of the subpoena that was served in the litigation.</p> <p>19 This is the most recent version. It's been amended</p> <p>20 several times. And if you look at the Exhibit A --</p> <p>21 Here's a copy for you, Randy.</p> <p>22 MR. HOPPER: Okay.</p> <p>23 (Sher Exhibit No. 5, five-page document</p> <p>24 entitled Subpoena in a Civil Case to Neal A. Sher,</p> <p>25 was marked for identification.)</p> |

17 (Pages 62 to 65)

| | |
|--|--|
| <p style="text-align: right;">66</p> <p>1 BY MS. LESKIN:</p> <p>2 Q. If you look at Exhibit A, which is the</p> <p>3 documents that were requested, number one is all</p> <p>4 documents and materials published or unpublished on</p> <p>5 which you intend to rely as a basis in whole or in part</p> <p>6 for the opinions you intend to express in this</p> <p>7 litigation.</p> <p>8 MR. HOPPER: Well, sure. Yeah. Yeah.</p> <p>9 BY MS. LESKIN:</p> <p>10 Q. And I assume that you are relying on your notes</p> <p>11 from your office visit with Mr. Martin and Mr. Stanley</p> <p>12 in reaching your opinions?</p> <p>13 A. In part, yes.</p> <p>14 MR. HOPPER: And I -- and I apologize. I -- I</p> <p>15 don't apologize, but I just didn't recall seeing</p> <p>16 anything where there was a specific request for</p> <p>17 their specific charts.</p> <p>18 MS. LESKIN: Okay.</p> <p>19 THE WITNESS: But I brought them.</p> <p>20 MS. LESKIN: Okay. So during a break, again,</p> <p>21 I'll take a look at those.</p> <p>22 THE WITNESS: Sure.</p> <p>23 BY MS. LESKIN:</p> <p>24 Q. Between August 2008 and November of 2008, there</p> <p>25 are several entries here for reviewing depositions and</p> | <p style="text-align: right;">68</p> <p>1 Q. Did you read through the judge's order that he</p> <p>2 issued?</p> <p>3 A. I did.</p> <p>4 Q. You also have some entries here about phone</p> <p>5 calls with Steven -- with attorneys and with Steven</p> <p>6 Grosser, M.D.? Who is Steven Grosser?</p> <p>7 A. Dr. Grosser is a local ophthalmologist who</p> <p>8 specializes in neuroophthalmology.</p> <p>9 Q. And what was the purpose of talking to Dr.</p> <p>10 Grosser?</p> <p>11 A. At the time, those times we were trying to find</p> <p>12 several neuroophthalmologists to assist with the case,</p> <p>13 and I made some calls.</p> <p>14 Q. Okay. And Dr. Nicholas Schmidt? Is that the</p> <p>15 same thing?</p> <p>16 A. Yes. I can't -- I didn't know him. He's -- he</p> <p>17 practices in town, I believe.</p> <p>18 MR. HOPPER: For clarification, that was after</p> <p>19 we discovered the mishap with Dr. --</p> <p>20 MS. LESKIN: That's fine.</p> <p>21 MR. HOPPER: -- Roth -- Roden -- Ruben --</p> <p>22 THE WITNESS: Rubenfeld.</p> <p>23 MR. HOPPER: -- Rubenfeld --</p> <p>24 THE WITNESS: I'm sorry.</p> <p>25 MR. HOPPER: -- and we were trying to inquire</p> |
| <p style="text-align: right;">67</p> <p>1 reports from various experts --</p> <p>2 A. Yes.</p> <p>3 Q. -- in the litigation, including the deposition</p> <p>4 of Dr. Aruna --</p> <p>5 A. I'm -- I'm sorry.</p> <p>6 Q. I'm sorry. Dr. Aruna --</p> <p>7 A. Mr. Hopper was coughing.</p> <p>8 Q. Dr. Aruna, Dr. Hayreh, Dr. McGwin, Dr.</p> <p>9 Pomeranz, Dr. Gotz, Dr. Gamel, and Dr. Kimmel.</p> <p>10 A. I believe those were reports --</p> <p>11 Q. Okay.</p> <p>12 A. -- as opposed to depositions.</p> <p>13 Q. Except for Dr. Aruna, who you specifically</p> <p>14 mentioned was a deposition?</p> <p>15 A. Yeah. And I could have been wrong.</p> <p>16 Occasionally I will write report for deposition, but --</p> <p>17 but, yes.</p> <p>18 Q. Okay. And you also have some entries that say</p> <p>19 "Review of Daubert Challenge." What does that refer</p> <p>20 to?</p> <p>21 A. I believe that both the plaintiff and the</p> <p>22 defendants here filed the Daubert challenges with Judge</p> <p>23 Magnuson. And I -- I read through those.</p> <p>24 Q. Through the briefs?</p> <p>25 A. Yes.</p> | <p style="text-align: right;">69</p> <p>1 --</p> <p>2 MS. LESKIN: Just trying to figure out who</p> <p>3 these were.</p> <p>4 MR. HOPPER: Yeah, I under -- I appreciate it.</p> <p>5 BY MS. LESKIN:</p> <p>6 Q. Brian Younge -- Younge?</p> <p>7 A. Yes, Dr. Younge is the head of</p> <p>8 Neuroophthalmology at the Mayo Clinic and someone I've</p> <p>9 known for about 30 years professionally, and I called</p> <p>10 him to see if he had involvement. I don't recall, to</p> <p>11 be honest, what the outcome of that call was.</p> <p>12 Q. Now the first entry you have for the report --</p> <p>13 for a report is dated November 25th, 2008, where you</p> <p>14 say, "Finish reports Mr. Martin and Stanley?"</p> <p>15 A. Right.</p> <p>16 Q. Had you drafted the reports before that date?</p> <p>17 A. I had started to and dictated them, yes.</p> <p>18 Q. Okay. And did you review the drafts that you</p> <p>19 had created with Mr. Hopper or Ms. Hauer?</p> <p>20 A. Ms. who?</p> <p>21 MR. HOPPER: Staci.</p> <p>22 BY MS. LESKIN:</p> <p>23 Q. Staci Hauer.</p> <p>24 A. Oh. It is -- WHEN I was asked to examine the</p> <p>25 patients, initially, I didn't really make any comments.</p> |

18 (Pages 66 to 69)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|--|---|
| <p style="text-align: right;">70</p> <p>1 It was more for findings. As a rule, I don't keep 2 drafts. It just creates too much paperwork, and I -- I 3 don't keep them. 4 I asked Mr. Hopper if he wanted me to opine, 5 and I wanted to clarify what my role was. It wasn't 6 quite clear. I was examining these patients, and I 7 wanted to know did he want me to state just their 8 findings, that they came in and they couldn't see, or 9 did they want me -- and what the diagnosis was and what 10 the prognosis is, and did he want me to give my best 11 opinion about the etiology and -- and what caused this 12 problem. 13 And in my initial draft, which was essentially 14 the same except for discussion, I didn't put the 15 discussion in it, because I just wasn't sure what my 16 role was. And it was clarified by either Mr. Hauer -- 17 or Ms. Hauer or Mr. Hopper, and -- and I wrote the 18 final draft that you have there that included my -- my 19 opinions. 20 Q. So the section of your report that's labeled 21 Discussion, that was created after the discussions with 22 Mr. Hopper or Ms. Hauer? 23 A. Yes. 24 Q. Okay. 25 A. That's the best I can remember how it happened.</p> | <p style="text-align: right;">72</p> <p>1 Q. Did you speak with any of Mr. Martin's 2 physicians before creating this report? 3 A. No. 4 Q. Since creating the report, have you spoken with 5 any of Mr. Martin's phys -- physicians? 6 A. About Mr. Martin? 7 Q. About Mr. Martin. 8 A. No. 9 Q. About the litigation in general? 10 A. No. 11 Q. Have you ever spoken with any -- any of Mr. 12 Stanley's physicians? 13 A. No. Not about the case, but I do know most of 14 these people involved, and I'm sure I've had 15 discussions with them about -- 16 Q. But not about Mr. Stanley? 17 A. I did not, no. 18 Q. And since writing your report, have you had any 19 conversations with Mr. Stanley's physicians about Mr. 20 Stanley or the litigation? 21 A. No. I didn't see my role, Ms. Leskin, as a 22 treating physician. It was more of a one-time 23 evaluation. 24 Q. Okay. Now I want to talk a little bit about 25 NAION. And when I say NAION, you understand I mean</p> |
| <p style="text-align: right;">71</p> <p>1 Q. On December 1st, 2008, you have an entry that 2 reads, "Revised Draft Report Discussion." Who was that 3 discussion with on December 1st, 2008? 4 A. That's my discussion within the report. 5 Q. Okay. So that's your creation of the 6 Discussion section of the report? 7 A. Yeah. I think there was some -- 8 MR. HOPPER: Not an oral discussion you had 9 with anyone? 10 MS. LESKIN: Okay. 11 THE WITNESS: No, no. No, no. I'm sorry. 12 That log is just for me to remember what I did. 13 BY MS. LESKIN: 14 Q. Okay. 15 A. I'm -- you know -- not an attorney, and I don't 16 quite know how to do the billing. 17 Q. That's fine. I just wanted to make sure I 18 understand. 19 MR. HOPPER: You -- you don't do as good as Ms. 20 Leskin does? 21 THE WITNESS: Well ... 22 SPECIAL MASTER BORG: We call -- we call it 23 deliberation. 24 MR. HOPPER: That's right. 25 BY MS. LESKIN:</p> | <p style="text-align: right;">73</p> <p>1 non-arteritic anterior ischemic optic neuropathy; 2 right? 3 A. NAION will be easier for the court reporter. 4 Q. Yes. It will be easier for me, as well. 5 A. In cap -- in capitals, by the way. 6 THE COURT REPORTER: Thank -- thank you. 7 MS. LESKIN: N-A-I-O-N. 8 THE COURT REPORTER: Thank you. 9 BY MS. LESKIN: 10 Q. Now NAION is a type of optic neuropathy; 11 correct? 12 A. Yes. 13 Q. And that simply means it's an insult to the 14 optic nerve; correct? 15 A. Yes. 16 Q. And would you agree with me that it's the most 17 common optic neuropathy in men over 50? 18 A. Yes. But not very common. 19 Q. All things are relative; right? 20 Now we call it anterior because the nerve 21 damage occurs in the anterior portion of the optic 22 nerve; right? 23 A. You're right. 24 Q. And that's the portion right behind the 25 eyeball; correct?</p> |

19 (Pages 70 to 73)

| | |
|---|---|
| <p style="text-align: right;">74</p> <p>1 A. Right flush with the eyeball, correct. That's</p> <p>2 how it's generally divided. And posterior would be</p> <p>3 further back on the optic nerve.</p> <p>4 Q. And did -- The term includes the word</p> <p>5 "ischemia," ischemic optic neuropathy, and that implies</p> <p>6 that there's a loss of blood flow to the optic nerve;</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. But do -- Would you agree with me that --</p> <p>10 A. Excuse me. Can I -- I just want to --</p> <p>11 Q. Absolutely.</p> <p>12 A. -- clarify. It's a lack of perfusion of the</p> <p>13 optic nerve. And sometimes blood flow and perfusion,</p> <p>14 although they may be related and may be sometimes used</p> <p>15 interchangeably, are not the same thing. You can have</p> <p>16 good blood flow, and the nerve is not perfused.</p> <p>17 Someone can have low hemoglobin, not enough oxygen in</p> <p>18 their optic nerve or live in Denver and be high up.</p> <p>19 But -- so I -- I don't want to use them</p> <p>20 interchangeably, but --</p> <p>21 Q. Okay.</p> <p>22 A. -- but I think I understand what your question</p> <p>23 is.</p> <p>24 Q. So -- so to clarify, and thank you for the</p> <p>25 clarification, the ischemia refers to a lack -- lack of</p> | <p style="text-align: right;">76</p> <p>1 But when they do come, and depending on the</p> <p>2 acuteness of the issue, sometimes there's clinical</p> <p>3 characteristics that might distinguish certain types</p> <p>4 of -- of ischemic optic neuropathies from others.</p> <p>5 Q. Five years after the insult, is it possible to</p> <p>6 look in the eye and tell the difference of the kind of</p> <p>7 optic neuropathy?</p> <p>8 A. No.</p> <p>9 Q. Do you agree with me that for each case of</p> <p>10 NAION, there's some variation from patient to patient?</p> <p>11 A. There's always variation. That's -- that's</p> <p>12 what makes medicine interesting.</p> <p>13 Q. The location of the visual defect might be</p> <p>14 different; correct?</p> <p>15 A. It -- it -- it varies from patient to patient,</p> <p>16 correct.</p> <p>17 Q. And the degree of visual loss varies from</p> <p>18 patient to patient?</p> <p>19 A. It does.</p> <p>20 Q. The progression differs from patient to</p> <p>21 patient?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Once there's been the insult to the</p> <p>24 optic nerve, is NAION a disease that comes and goes, or</p> <p>25 do you have it and that's it?</p> |
| <p style="text-align: right;">75</p> <p>1 oxygenation to the optic nerve?</p> <p>2 A. Yes, as -- as a final insult.</p> <p>3 Q. Okay. But -- but how that happens, that's not</p> <p>4 quite known in medical science; correct?</p> <p>5 A. It's postulated, yes.</p> <p>6 Q. There's hypotheses out there; correct?</p> <p>7 A. Correct.</p> <p>8 Q. And different people have different theories as</p> <p>9 to how that might occur; correct?</p> <p>10 A. I think there's fairly good agreement that</p> <p>11 NAION is a lack of perfusion and anoxia of -- of the</p> <p>12 optic nerve in terms of -- of one of its causes, but</p> <p>13 there are other causes of NAION that don't have</p> <p>14 anything to do necessarily with circulation. There's</p> <p>15 drug-induced NAION from a drug called ethambutol. And</p> <p>16 that doesn't really have to do with circulation. It</p> <p>17 has to do with chemical toxicity.</p> <p>18 Q. When you look in the eye, can you tell the --</p> <p>19 which type of optic neuropathy you're dealing with?</p> <p>20 A. To -- to some degree, you can. Most of the</p> <p>21 time, we don't look in the eye before things happen,</p> <p>22 because people don't come running to the</p> <p>23 ophthalmologist. We're hard to get to see sometimes,</p> <p>24 and we're not convenient. And it takes a long time to</p> <p>25 get an appointment usually.</p> | <p style="text-align: right;">77</p> <p>1 A. Usually, once the insult to the optic nerve is</p> <p>2 there, there's a progression towards whatever damage</p> <p>3 it's going to be. It's -- it's much like a cascade.</p> <p>4 And once that cascade starts, things happen. It's --</p> <p>5 it's -- that -- and I don't want to get into the</p> <p>6 pathogenesis, but once the nerve has -- is insulted, it</p> <p>7 can swell. The nerve is constricted. There's --</p> <p>8 Nerve is like a telephone cable, and it's got a</p> <p>9 tight binding, and there's constrictions at certain</p> <p>10 points. So once there's swelling in the nerve, it's</p> <p>11 like if you bruised your hand and tightly wrapped it,</p> <p>12 that swelling could be made worse if you can't get</p> <p>13 the -- you know -- you can compress a nerve.</p> <p>14 So a chain of events happens. It's variable</p> <p>15 from individual to individual what happens afterwards.</p> <p>16 It can recur. You know, there are cases where NAION,</p> <p>17 you have one episode in the same eye, and it's possible</p> <p>18 to have another episode in the same eye. There have</p> <p>19 been case reports of that.</p> <p>20 Q. It's also possible to have an episode in the</p> <p>21 other eye?</p> <p>22 A. Yes.</p> <p>23 Q. And that occurs -- That's certainly a potential</p> <p>24 sequela of -- of the NAION in one eye; right?</p> <p>25 A. Yes.</p> |

20 (Pages 74 to 77)

| | |
|---|---|
| <p style="text-align: right;">78</p> <p>1 MR. OVERHOLTZ: Object to form; lack of 2 foundation. 3 SPECIAL MASTER BORG: Okay. I'll sustain that. 4 More foundation. 5 MS. LESKIN: Okay. We'll come back to that. 6 BY MS. LESKIN: 7 Q. When someone has isch -- a NAION event in one 8 eye, are they at risk for a NAION event in the other 9 eye? 10 A. Yes. 11 Q. And do you have an opinion as to the percentage 12 increased risk they have for a NAION event in that 13 second eye? 14 MR. OVERHOLTZ: Object to form. I would just 15 like her to clarify a time frame. 16 SPECIAL MASTER BORG: Okay. 17 MR. OVERHOLTZ: Within life? Within so many 18 years? What are we talking about? 19 SPECIAL MASTER BORG: Well, it doesn't sound 20 like it's an objection. You just want a 21 clarification. Yeah. Fair enough. 22 MS. LESKIN: Okay. 23 SPECIAL MASTER BORG: Can you -- can you get 24 that? 25 BY MS. LESKIN:</p> | <p style="text-align: right;">80</p> <p>1 that with NAION you have the swollen disc in its acute 2 state; correct? 3 A. Usu -- Yes. 4 Q. And -- and when you go to the -- the doctor and 5 you look in a patient's eye, in fact, that's what 6 you're going to see; correct? A swollen disc in the 7 back? 8 A. Yes. 9 Q. Is it possible to have a swollen disc but no 10 visual field defect, no loss of vision? 11 A. Yes. 12 Q. And -- and how often does that occur? 13 A. I -- I can't break it down into a percent, but 14 we frequently see swollen disks and no visual loss. I 15 have -- a -- a classic example is pseudotumor, which is 16 an elevation in intraocular pressure. Cause is 17 unknown. And people have very swollen optic nerves -- 18 you know -- they jump out at you. And they usually 19 have no significant visual loss. 20 Q. And if we focus that specifically on NAION, is 21 it possible to have a swollen disc as the first sign of 22 NAION, but a patient not having any visual loss? 23 A. Yes. I think the best way to look at this is 24 there is a big variation in terms of what you see in 25 the disc and visual loss.</p> |
| <p style="text-align: right;">79</p> <p>1 Q. Well, let me ask you this. Is it -- Let's 2 start with lifetime. Over time, is there an -- can you 3 quantify the increased risks to an ischemic event or a 4 NAION event in the second eye? 5 A. Most all of the studies I have seen have a 6 definite starting and ending date in terms of 7 statistics. And I think the best statistics are in the 8 optic nerve decompression study, which was a study 9 where patients were randomized into the surgical 10 procedure where they -- I'm sorry. 11 Q. No. Go ahead. 12 A. -- optic nerve was opened and decompressed, the 13 sheath, or not. And in that study, approximately 20 to 14 25 percent, depending on how you defined -- Some people 15 had both events when they started. It was complex. I 16 think the generally-agreed figure is about 25 percent 17 of people over at least five years may get a second 18 attack. 19 Q. And -- and you said over five years. But that 20 range varies greatly; correct? 21 A. It does. 22 Q. And in fact, I've seen figures that have it as 23 low as 16 days or as much as six years or more? 24 A. I think that's a fair statement. 25 Q. Is it possible to have -- you -- you mentioned</p> | <p style="text-align: right;">81</p> <p>1 The other thing that I think is important for 2 the Court or the -- 3 Q. Mmm-hmm. 4 A. -- if this is a Court -- to understand is that 5 patients are just poor reporters of visual loss. 6 And -- and I can't tell you how often I have people 7 come in, and they literally couldn't see the big E on 8 the chart with one eye, and they didn't know that. 9 They came in because their eye was tearing or they had 10 a pimple on their eyelid. And you come in and said, 11 "How long have you not been seeing out of your 12 right eye," and they said, "I don't know." So unless 13 you sort of do studies where you carefully follow 14 people, I expect anything when I speak to patients 15 about visual loss. 16 It's amazing. You would think that that would 17 be something that people would notice right away. But 18 you would be amazed, after 30 years of practicing 19 ophthalmology, the variation in that. 20 Q. To further that point, I'm going to mark as 21 Exhibit 6 an article entitled "Hypothesis: A Venous 22 Etiology for Non-Arteritic Anterior Ischemic Optic 23 Neuropathy" by Drs. Levin and Danesh-Meyer. And you've 24 seen that article before; right? 25 A. I have.</p> |

21 (Pages 78 to 81)

| | |
|---|---|
| <p style="text-align: right;">82</p> <p>1 (Sher Exhibit No. 6, four-page article entitled</p> <p>2 Hypothesis, A Venous Etiology for Nonarteritic</p> <p>3 Anterior Ischemic Optic Neuropathy, by Leonard A.</p> <p>4 Levin, M.D., Ph.D., Helen V. Danesh-Meyer, FRANZCO,</p> <p>5 was marked for identification.)</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. That's the Levin editorial that we were talking</p> <p>8 about before?</p> <p>9 A. Yes.</p> <p>10 Q. If you look at the page that's marked 1582,</p> <p>11 which is the front page of that --</p> <p>12 A. Yes.</p> <p>13 Q. -- and if you look at the left-hand column on</p> <p>14 the bottom, the paragraph that starts, "Furthermore?"</p> <p>15 A. Yes.</p> <p>16 Q. And that second sentence says, "For example,</p> <p>17 patients often have asymptomatic disc edema for weeks</p> <p>18 to months before visual loss ensues." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And is that your experience in patients with</p> <p>21 NAION?</p> <p>22 A. It is. It was described by Dr. Hayreh in his</p> <p>23 definitive articles on NAION.</p> <p>24 Q. And, in fact, Dr. Hayreh just published an</p> <p>25 article recently on incipient NAION as he called it;</p> | <p style="text-align: right;">84</p> <p>1 examination from an ophthalmologist standpoint?</p> <p>2 MS. LESKIN: Yes.</p> <p>3 MR. OVERHOLTZ: Or his knowledge -- other --</p> <p>4 Okay.</p> <p>5 MS. LESKIN: Based on his examination.</p> <p>6 THE WITNESS: I wonder if you would just repeat</p> <p>7 the question --</p> <p>8 MS. LESKIN: Sure.</p> <p>9 THE WITNESS: -- so I can give an accurate</p> <p>10 answer.</p> <p>11 BY MS. LESKIN:</p> <p>12 Q. Sure. Based on your examination only of Mr.</p> <p>13 Martin from when you looked into his eye, were you able</p> <p>14 to tell how much time had passed between the time of</p> <p>15 the insult to the optic nerve and his loss of vision?</p> <p>16 A. No. There would be, based on my examination</p> <p>17 findings alone, it's sort of looking like a building</p> <p>18 that's burnt down by the fire, and you can't tell</p> <p>19 always how long the fire has been there. When I see</p> <p>20 optic atrophy, it could have been there a year. It</p> <p>21 could have been there five years. So just based on</p> <p>22 looking at the nerve, it's difficult to -- to tell the</p> <p>23 time course.</p> <p>24 Q. And when you examined Mr. Stanley, same thing,</p> <p>25 you couldn't tell how much time had passed between the</p> |
| <p style="text-align: right;">83</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And that's No. 6 on her list of ref -- Dr.</p> <p>4 Levin's ref -- references?</p> <p>5 A. Yes.</p> <p>6 Q. So when a patient comes into your office</p> <p>7 complaining of visual loss, and you see the swollen</p> <p>8 optic nerve that looks like NAION to you, can you tell</p> <p>9 with any degree of certainty when that NAION began?</p> <p>10 A. It's sometimes difficult if you just see</p> <p>11 swelling. Usually, patients don't come in until they</p> <p>12 have visual loss. That's -- that's what brings them</p> <p>13 in. I -- I can't remember anybody coming in with NAION</p> <p>14 that -- that -- that just -- that had it and didn't</p> <p>15 know there was something. But it's -- it's a big</p> <p>16 variation in presentation, yes.</p> <p>17 Q. And can you tell by looking in the eye how long</p> <p>18 it's been since that edema started?</p> <p>19 A. No. It -- I cannot.</p> <p>20 Q. And when you examined Mr. Martin, were you able</p> <p>21 to tell with any certainty how much time had passed</p> <p>22 between the injury to the optic nerve and his loss of</p> <p>23 vision?</p> <p>24 MR. OVERHOLTZ: Object to form. Are -- are you</p> <p>25 asking the doctor from actual -- just from his</p> | <p style="text-align: right;">85</p> <p>1 insult to his optic nerve and his loss of vision; is</p> <p>2 that fair?</p> <p>3 A. Well, based on -- on examination. But the</p> <p>4 question is -- is -- is somewhat misleading. Can I</p> <p>5 make a reasonable conclusion to a degree of scientific</p> <p>6 and medical certainty what happened in these events</p> <p>7 based on talking to him, reviewing the records, looking</p> <p>8 at it? The answer is yes, I did.</p> <p>9 Can I just take that isolated finding and know</p> <p>10 what the timing is? No.</p> <p>11 Q. Okay. And we'll come back to the rest of that.</p> <p>12 A. Sure.</p> <p>13 Q. But based solely on examination, you can't make</p> <p>14 that conclusion; correct?</p> <p>15 MR. OVERHOLTZ: Object to the form; asked and</p> <p>16 answered. He answered the question accurately.</p> <p>17 SPECIAL MASTER BORG: The -- I understand the</p> <p>18 objection. Sustained.</p> <p>19 BY MS. LESKIN:</p> <p>20 Q. What are some of the risk factors that you</p> <p>21 understand of NAION -- or for NAION?</p> <p>22 A. Usually, the risk factors are older individuals</p> <p>23 that have some tendency towards cardiovascular disease.</p> <p>24 I think someone referred to it as vasculopathic. I</p> <p>25 hadn't really seen that term before, but I think it's a</p> |

22 (Pages 82 to 85)

| | |
|---|---|
| <p style="text-align: right;">86</p> <p>1 good description, meaning their vessels are brittle, 2 have problems with arteriosclerosis, have troubles with 3 autoregulation. These patients are usually 4 hypertensive. They may be diabetic. They usually 5 could have an abnormal lipid profile. They tend to be 6 older. And they usually are on some treatment for 7 blood pressure medication, frequently. 8 Q. Would you agree with me that this list that 9 you've just provided me of risk factors for NAION are 10 also risk factors for erectile dysfunction? 11 A. Yes. 12 Q. And if a patient came into your office over age 13 50 with vasculopathic risk factors such as you've 14 described or is taking no other medications, what would 15 you say caused his NAION? 16 A. I -- I'm -- I'm sorry. I just -- So a patient 17 comes into my office. You -- I'm sorry -- with -- 18 Q. Sure. I'll -- 19 A. With no other risk factors -- no risk factors 20 or -- 21 Q. I'll -- I'll -- a patient -- 22 A. I'm -- I'm sorry. I don't -- 23 Q. That's okay. 24 A. Repeat it. 25 Q. A patient comes into your office, age over 50</p> | <p style="text-align: right;">88</p> <p>1 answer if you -- if you -- Do you understand the 2 question? 3 THE WITNESS: I think I do. 4 SPECIAL MASTER BORG: Okay. 5 THE WITNESS: And the answer is no, it would 6 not be unusual. 7 BY MS. LESKIN: 8 Q. Is that a pretty common presentation for NAION? 9 A. The presentation would be someone would come in 10 with a swollen nerve and vision loss. And typically, 11 they would be over 50. And they might be hypertensive 12 or a little overweight, and high cholesterol. The 13 answer is yes. 14 Q. Is it your opinion that a causal relationship 15 between Viagra and NAION generally has been 16 established? 17 A. I'm sorry. Was there a causal -- 18 Q. Is it your opinion that a causal relationship 19 between Viagra and NAION has been established? 20 MR. OVERHOLTZ: Object to form. 21 SPECIAL MASTER BORG: Over -- Do you understand 22 the question, Doctor? 23 THE WITNESS: I'd like to -- Ms. Leskin -- to 24 define "causal," if she would. 25 SPECIAL MASTER BORG: Okay. Fair enough.</p> |
| <p style="text-align: right;">87</p> <p>1 with vasculopathic risk factors taking no other 2 medications, what would you say caused his NAION? 3 MR. OVERHOLTZ: Object to form; lack of 4 foundation. 5 SPECIAL MASTER BORG: Overruled. 6 THE WITNESS: I think the ultimate problem is 7 hypoperfusion and ischemia of the optic nerve due to 8 lack of oxygenation of the nerve. And at some 9 point, there was an insult to that optic nerve in -- 10 in that particular patient. 11 BY MS. LESKIN: 12 Q. And could you say with any degree of medical 13 certainty in the patient I've just described what that 14 insult was? 15 A. In a general patient like that, it would be 16 difficult to ascribe one insult -- and I think it was 17 the -- an accumulation of multiple causes. 18 Q. If a patient like that came into your office 19 over age 50 with vasculopathic risk factors with NAION, 20 that's not a situation that would be unusual in your 21 opinion, is it? 22 A. No. 23 MR. OVERHOLTZ: Object to form. 24 THE WITNESS: I'm sorry. 25 SPECIAL MASTER BORG: Overruled. You may</p> | <p style="text-align: right;">89</p> <p>1 BY MS. LESKIN: 2 Q. Okay. Well, let me ask you a question. How do 3 you define cause as a medical doctor? 4 A. I think we take the totality of evidence at the 5 given time in the clinical situation where if -- to be 6 specific about Mr. Martin, Mr. Stanley, the entirety of 7 all the facts we can draw, and then to say is it 8 reasonable to assume that the use of this drug 9 contributed to this problem. And the answer, what I've 10 written is yes. 11 In all cases of NAION, in all cases of people 12 using erectile dysfunction drugs, PD-5 inhibitors, I 13 can't say -- I -- I certainly -- not all cases of NAION 14 are from PD-5 inhibitors, and probably not all cases of 15 NAION when people were using these drugs were from 16 them. But I'm limiting my discussion here to the two 17 specific cases that I have been asked to opine on. 18 Q. So you'll agree with me that men get NAION who 19 have never taken Viagra; correct? 20 A. Men were getting NAION before Viagra was 21 invented, yes. 22 Q. And even today, since Viagra has been invented, 23 there are patients who don't take Viagra who get NAION; 24 correct? 25 A. Sure. Yes.</p> |

23 (Pages 86 to 89)

| | |
|---|--|
| <p style="text-align: right;">90</p> <p>1 Q. And as you mentioned, there are people who take 2 the drug and get NAION and it may have nothing to do 3 with the drug; correct? 4 A. It's a possibility. 5 Q. Are you aware of any clinical study 6 demonstrating that men taking Viagra are at an 7 increased risk for NAION as compared to men who don't 8 take Viagra? 9 A. There are studies that help support. I don't 10 think there's any definitive study. Again, we're 11 looking at this in the totality. We're looking at it 12 and understanding the disease, what we think causes it. 13 This is still a hypothesis. No one has been able to 14 say -- like strep throat is caused by strep bacteria. 15 I think NAION is -- is more complex than that. 16 But when you take the disease, the 17 pathophysiology or understanding, the particular 18 circumstances of each individual case, the relationship 19 in general between taking the medications when they 20 take them, what we understand the -- the issues are in 21 causing the optic nerve ischemia, I think you can make 22 good conclusions. 23 You also have to keep in mind the difficulty of 24 reporting cases of when people use the drug and not. 25 And I was -- Since I became involved with this, I would</p> | <p style="text-align: right;">92</p> <p>1 won't repeat again, is very variable. A lot of people 2 just don't come in complaining of visual loss as much 3 and don't know they have it until they -- it really 4 goes bad. 5 MS. LESKIN: Objection; non-responsive. 6 SPECIAL MASTER BORG: Sustained. 7 BY MS. LESKIN: 8 Q. Doctor, are you aware of any clinical study 9 that shows that men taking Viagra are at an increased 10 risk for NAION as compared to men who don't take 11 Viagra? 12 MR. OVERHOLTZ: Ms. Leskin, are you trying to 13 repeat the same question you asked before? 14 Are you repeating the last question? 15 THE WITNESS: Sorry. 16 SPECIAL MASTER BORG: No, no, that's all right. 17 Hang on. 18 MR. OVERHOLTZ: I just want to make sure we're 19 on the same -- make sure the doctor's not confused 20 on what the question is, because the last question 21 was a different question. 22 MS. LESKIN: No, it's the same question. 23 MR. OVERHOLTZ: The last question was about ED, 24 and now you're asking about Viagra. 25 BY MS. LESKIN:</p> |
| <p style="text-align: right;">91</p> <p>1 specifically ask individuals who write down -- men who 2 come to my office who write down their medicines every 3 day, and I just wanted to do my own little unofficial 4 survey in my head of how many would write down that 5 they were taking a ED drug. And I've asked, I believe, 6 at least a hundred men that. They thought that maybe I 7 was a little crazy. But I -- I asked them 8 specifically. And I believe that -- First I'd ask what 9 medicines are you taking, because it wasn't written 10 down. And none of them -- excuse me -- one of them 11 wrote down Viagra because he had some blue 12 discoloration in his vision. But the other 99 I asked 13 did not write it down. 14 And then I went over their list of medicines. 15 I asked them specifically were you taking the drug, and 16 I would say five to ten had used the drug, either 17 Viagra or the two other compounds, and didn't put it 18 down either for shame. It's not something you want to 19 -- you know -- put in your local newspaper. Or a lot 20 of times, intermittent drug use, once a week, once a 21 month is not considered drug use, and they just don't 22 put it down. So the numbers in the epidemiology are 23 sometimes difficult. I think there's a lot -- there's 24 some different use. 25 And then visual loss, as I said before and</p> | <p style="text-align: right;">93</p> <p>1 Q. Well, if it was about ED, then I misspoke -- 2 MR. OVERHOLTZ: Okay. 3 MS. LESKIN: -- because his answer didn't 4 ask -- answer that one either. But let me be clear. 5 SPECIAL MASTER BORG: Let's get the question -- 6 MS. LESKIN: Let me -- 7 SPECIAL MASTER BORG: -- or get a question. 8 BY MS. LESKIN: 9 Q. Right. Doctor, are you aware of any clinical 10 study that shows that men who take Viagra are more at 11 risk for NAION than men who don't take Viagra? 12 A. Yes. 13 Q. Okay. What study is that? 14 A. There are more than one study. 15 Q. Okay. What studies are those? 16 A. The epidemiology studies in terms of asking 17 patients and specifically -- I'm sorry -- The one 18 referred to was from Dr. McGwin in terms of 19 epidemiology and numbers. And I'm referring to McGwin, 20 Vaphiades, Hall, and Owsley in The British Journal of 21 Ophthalmology. 22 There are a number of other case reports 23 talking about loss. There's a case report I was 24 particularly interested in a child taking Viagra for I 25 believe pulmonary hypertension who had NAION. And the</p> |

24 (Pages 90 to 93)

| | |
|--|--|
| <p style="text-align: right;">94</p> <p>1 authors couldn't find any other cause and attributed it 2 to the drug. 3 And there are other experts one way or the 4 other in various editorials who have opined that they 5 felt that the drug and related drugs were the cause of 6 NAION. 7 Q. Okay. We'll come back to all of those. I 8 spec -- specifically asked you about clinical studies. 9 Are you aware of any clinical -- Do you know what a 10 clinical study is? 11 A. Yeah. I believe where you could do a large 12 amount -- Well, there are all sorts of clinical 13 studies. And do you want to be more specific? 14 Q. Okay. But do you understand the clinical -- 15 when I say clinical study, to be clear, I'm referring 16 to a placebo-controlled study where you have some 17 patients taking a drug and some patients taking a 18 placebo and you see if they have an increased risk of a 19 disease in one group versus another. 20 A. Right. 21 Q. Right. Is that your understanding of a 22 clinical study? 23 A. It is. And it would be very -- 24 MR. OVERHOLTZ: I'm going to object to the -- 25 THE WITNESS: I'm sorry.</p> | <p style="text-align: right;">96</p> <p>1 the type of clinical study that would definitively 2 answer this question is to give a group of men the 3 drug or a placebo, follow them for three, five 4 years, whatever incidence. But because the 5 incidence of NAION is anywhere from 2.2 to 10.3 per 6 hundred thousand, the numbers that it would take to 7 run that study, I think you'd run out of older men 8 in the United States population. You would run out 9 of neuroophthalmologists, ophthalmologists, 10 statisticians, epidemiologists and the rest. So I 11 think that study would be virtually impossible. 12 BY MS. LESKIN: 13 Q. Okay. But that study hasn't been done; right? 14 A. Unless I'm not aware of it being done. 15 Q. Okay. And so to your knowledge, there's no 16 clinical study that shows that men who take Viagra are 17 at an increased risk for NAION as opposed to men who 18 don't take Viagra; correct? 19 MR. OVERHOLTZ: I'm going to object to form. 20 It lacks specificity with the term "clinical study." 21 And also, he just answered that one study would be 22 impossible and he's not aware of one. 23 SPECIAL MASTER BORG: Your objection is 24 overruled. 25 Can you answer the question, Doctor, or do you</p> |
| <p style="text-align: right;">95</p> <p>1 MR. OVERHOLTZ: -- form of the question, almost 2 lack of foundation. We have been doing this 3 litigation now for three years, and every witness 4 has testified that such a study is impossible. So 5 asking a question as to whether someone knows of the 6 existence of one is -- is crazy. 7 MS. LESKIN: I -- I don't believe that's a form 8 objection, Your Honor. 9 SPECIAL MASTER BORG: Well -- 10 MR. OVERHOLTZ: It's lack of foundation. No 11 foundation that one could exist. You can ask them 12 what they know about them and imply that therefore 13 there's no evidence when you know that one could not 14 exist? 15 MS. LESKIN: My -- my question actually was is 16 that what your understanding of a clinical study is. 17 SPECIAL MASTER BORG: That's my recollection of 18 the question, too. 19 THE WITNESS: And -- 20 SPECIAL MASTER BORG: So the objection is 21 overruled. 22 MR. OVERHOLTZ: I thought he already answered 23 that, but -- 24 THE WITNESS: Let me -- let me answer, please. 25 There are different types of clinical studies. And</p> | <p style="text-align: right;">97</p> <p>1 need it played back? 2 THE WITNESS: Am I aware of a clinical -- I 3 just want to clarify, Ms. Leskin, your -- your 4 question. Am I aware of a clinical study that 5 proved this association? And the answer is, if -- 6 going back to my previous answer, that clinical 7 study would be virtually impossible, and I'm not 8 aware of one. 9 BY MS. LESKIN: 10 Q. Okay. 11 I'm not -- And let me just be clear, because my 12 question didn't talk about one that proves the 13 association. Is there a clinical study out there that 14 shows that men who take Viagra are at an increased risk 15 for NAION as opposed to men who don't take Viagra? 16 A. The definitive study has not been done. 17 Q. Okay. 18 A. There are a lot of individual pieces of 19 evidence that I believe that conclusion can be made, 20 yes. 21 Q. Well -- 22 MR. OVERHOLTZ: I think it would help if you 23 would not use the term "clinical study." 24 MS. LESKIN: Well, I -- 25 MR. OVERHOLTZ: If you want to use double --</p> |

25 (Pages 94 to 97)

| | |
|--|---|
| <p style="text-align: right;">98</p> <p>1 MS. LESKIN: -- want to use the term "clinical 2 study." 3 MR. OVERHOLTZ: If you want to use blinded -- 4 double-blind placebo-controlled clinical trial, 5 that's one thing. 6 MS. LESKIN: Fine. You know what? I will ask 7 your question. 8 BY MS. LESKIN: 9 Q. Dr. Sher -- 10 A. Yes. 11 Q. -- are you aware of any double-blind 12 placebo-controlled study that shows that men who take 13 Viagra are at an increased risk for NAION as opposed to 14 men who don't take Viagra? 15 MR. OVERHOLTZ: I'm going to object to the form 16 again; lack of foundation that such a study is even 17 possible, and the testimony has proven that out. 18 There's a lack of foundation for this question. 19 MS. LESKIN: This would go much -- 20 SPECIAL MASTER BORG: It's -- it's -- 21 MS. LESKIN: -- quicker if everything wasn't 22 objected to. 23 SPECIAL MASTER BORG: Well, I don't need those 24 editorials. It's overruled. Doctor, let's have the 25 question back to you again if you need it.</p> | <p style="text-align: right;">100</p> <p>1 Q. Have you read Dr. McGwin's deposition in this 2 litigation? 3 A. Yes. 4 Q. Now he's been deposed twice. Have you read 5 both of them? 6 To simplify it, his second deposition was on 7 December 11th, 2008. 8 A. I know I've read his report. It -- I'm sorry; 9 I was confusing his report with his deposition. I -- I 10 don't believe I've read his deposition. 11 Q. Okay. 12 A. Thank you. I've read his report. Thank you. 13 Q. If you can turn to Table 2, which is on Page 14 155 of Dr. McGwin's report. 15 A. Yes. 16 Q. In looking at Viagra, you will see that the 17 Adjusted Odds Ratio is 1.75; correct? 18 A. Yes. 19 Q. And the P Value is .64 for that calculation; 20 correct? 21 A. Yes. 22 Q. And the confidence interval for Viagra use goes 23 from .48 to 6.30; correct? 24 A. Right. 25 Q. And you will agree with me that that's not a</p> |
| <p style="text-align: right;">99</p> <p>1 MS. LESKIN: Can you read the question back, 2 please? 3 THE COURT REPORTER: I'm not sure I can, but 4 I'll -- 5 THE WITNESS: I -- I can -- I can -- I can 6 answer it -- 7 THE COURT REPORTER: I'm sorry. 8 THE WITNESS: -- Ms. Leskin. No. 9 BY MS. LESKIN: 10 Q. You mentioned epidemiological studies. 11 A. Yes, ma'am. 12 Q. Okay. And you referred specifically to a study 13 by Dr. McGwin; correct? 14 A. Yes. 15 (Sher Exhibit No. 7, four-page extended report 16 entitled Non-arteritic anterior ischaemic optic 17 neuropathy and the treatment of erectile 18 dysfunction, was marked for identification.) 19 BY MS. LESKIN: 20 Q. Let me show you what we marked as Exhibit 7. 21 And that's an article by Dr. McGwin; correct? Dr. 22 McGwin, Vaphiades, Hall, and Owsley? 23 A. Correct. 24 Q. And is this the study you were referring to? 25 A. Yes.</p> | <p style="text-align: right;">101</p> <p>1 statistically significant finding; correct? 2 A. That's correct. 3 Q. And if you look at the abstract that was 4 prepared at the beginning of the article under Results, 5 the authors of this study concluded that overall, males 6 with NAION were no more likely to report a history of 7 Viagra or Cialis use compared with -- to similarly aged 8 controls? 9 A. I'm sorry. I don't quite see where you're 10 reading. 11 Q. Sure. The abstract at the top of the first 12 page, under Results. 13 MR. OVERHOLTZ: Results. 14 THE WITNESS: Under Results, I'm sorry. Yes. 15 BY MS. LESKIN: 16 Q. Right. The authors wrote, "Overall, males with 17 NAION were no more likely to report a history of Viagra 18 or Cialis use compared to similarly aged controls"; 19 right? That was the conclusions the authors wrote? 20 A. That was one of the conclusions. 21 Q. Okay. 22 A. You didn't read the rest. 23 Q. Okay. But I'm focusing on the overall 24 conclusion. Because you told me that this is one of 25 the studies that you looked at to support your view</p> |

26 (Pages 98 to 101)

| | |
|---|---|
| <p style="text-align: right;">102</p> <p>1 that it's been shown that Viagra -- that men who take 2 Viagra have an increased risk of NAION. 3 MR. OVERHOLTZ: Unfortunately, Ms. Leskin, you 4 don't get to dictate how the doctor reaches his 5 opinion. 6 SPECIAL MASTER BORG: Well, is that an 7 objection, or is that a comment, or what is it? 8 MR. OVERHOLTZ: Well -- well, it was her 9 statement. I'm focused on her -- She didn't ask a 10 question. She made an editorial, "I'm focused on 11 the whatever." 12 Well, I don't care what she's focused on. The 13 doctor focuses on his information that was in his 14 ability to form his opinion. And he already 15 testified he looked at the overall nature of all the 16 evidence. 17 SPECIAL MASTER BORG: All right. 18 MR. OVERHOLTZ: So she made a sentence. I made 19 a sentence. 20 SPECIAL MASTER BORG: Okay. Let's get a 21 question to the witness. 22 BY MS. LESKIN: 23 Q. That's the conclusion overall that Dr. McGwin 24 and his colleagues published; correct? 25 A. No.</p> | <p style="text-align: right;">104</p> <p>1 subgroups of men that are at risk, the association 2 is -- is much more strong. And I'm not a 3 statistician, but -- but Dr. McGwin is an expert. 4 And I agree with his conclusions. 5 MS. LESKIN: Move to str -- Objection; 6 non-responsive. 7 SPECIAL MASTER BORG: Sustained. 8 THE WITNESS: I -- 9 SPECIAL MASTER BORG: That's okay. 10 BY MS. LESKIN: 11 Q. Doctor, the conclusion that Dr. McGwin and his 12 colleagues published in The British Journal of 13 Ophthalmology for the overall study results, was that 14 men with NAI -- with NAION were no more likely to 15 report a history of Viagra or Cialis use compared to 16 similarly aged controls; correct? 17 MR. OVERHOLTZ: Are you reading from an 18 abstract? 19 MS. LESKIN: Yes. 20 THE WITNESS: That's what he wrote for the 21 overall group, yes. 22 BY MS. LESKIN: 23 Q. Okay. Would you agree with me that in order to 24 cause an event, a drug must have been taken before the 25 event?</p> |
| <p style="text-align: right;">103</p> <p>1 Q. Is that the overall finding? I didn't read -- 2 A. I'll -- I'll read -- 3 Q. -- the overall finding? 4 A. His overall finding is, "For men with a history 5 of myocardial infarction or hypertension, the use of 6 Viagra or Cialis may increase the risk of NAION. 7 Physicians prescribing these medications to patients 8 with these conditions should warn them about the 9 potential risk of NAION." 10 So when I -- when I read this and I looked at 11 the sub groups, and, again, we're talking about a 12 relatively rare disease, fortunately, otherwise, we'd 13 have too many blind men going around, I looked at this 14 as -- as evidence that there was an association for 15 particular groups, but which -- 16 THE COURT REPORTER: I'm sorry. That there was 17 an association? 18 THE WITNESS: I'm sorry. Was an association 19 for particular groups, particularly people that had 20 high blood pressure, myocardial infarction, and, 21 overall, there wasn't, much like in Pfizer's initial 22 study of 7 or 8,000 patients. They didn't find it. 23 But with an instance of one -- 2.2 in a hundred 24 thousand or ten, depending, we probably wouldn't. 25 But we're dealing, when we go to these</p> | <p style="text-align: right;">105</p> <p>1 A. The basic -- I would say the basic definition 2 is true. But if an event such as a herpes infection of 3 the cornea was an event, and a drug was then given, and 4 the infection got worse, because it's like gasoline on 5 a fire, that would also -- you know -- there are things 6 can be ongoing to make it worse. 7 But in general, in terms of the epidemiology 8 and the -- and the tenets of what causes things, the 9 drug should be given before the event. 10 Q. Okay. And if we -- 11 A. There are -- there are drugs that are given 12 during events that can make things worse, and I just 13 want to -- 14 Q. Okay. 15 A. -- clarify that. 16 Q. Well, let's be more specific then. Let's talk 17 specifically about Viagra and NAION. 18 A. Sure. 19 Q. In order for Viagra to have caused NAION, it 20 must have been taken before the NAION occurred; 21 correct? 22 A. Yes. 23 Q. And if the NAION occurs before the medication 24 has even been taken, whatever caused the NAION, it 25 wasn't Viagra; right?</p> |

27 (Pages 102 to 105)

| | |
|---|--|
| <p style="text-align: right;">106</p> <p>1 A. If NAION occurred before and it was</p> <p>2 specifically diagnosed, I would agree with your</p> <p>3 statement, yes.</p> <p>4 Q. Okay. I want you to look at Page 156 of Dr.</p> <p>5 McGwin's article. Do you see at the very bottom of the</p> <p>6 left-hand column the sentence that starts with,</p> <p>7 "However"?</p> <p>8 A. Bottom of the left-hand --</p> <p>9 MR. OVERHOLTZ: On the very bottom?</p> <p>10 MS. LESKIN: The very bottom of the left-hand</p> <p>11 column that starts with -- the sentence that starts</p> <p>12 with --</p> <p>13 THE WITNESS: Yes, yes, yes.</p> <p>14 BY MS. LESKIN:</p> <p>15 Q. -- "However"?</p> <p>16 A. Yes, ma'am.</p> <p>17 Q. And Dr. McGwin and his colleagues wrote,</p> <p>18 "However, when defining the primary exposure variable,</p> <p>19 that is, Viagra and/or Cialis use, we were able to</p> <p>20 define as exposed only those subjects who reported</p> <p>21 using Viagra and/or Cialis before a NAION diagnosis";</p> <p>22 right? That's what Dr. McGwin wrote in the article?</p> <p>23 A. Yes, he did.</p> <p>24 Q. And that would be an important factor for you</p> <p>25 to consider when judging this article; right?</p> | <p style="text-align: right;">108</p> <p>1 McGwin's deposition, and I -- I was not sent it.</p> <p>2 Q. Okay. So no one --</p> <p>3 A. I did read his report.</p> <p>4 Q. Did you --</p> <p>5 A. Doctor --</p> <p>6 Q. Did you read Dr. Kimmel's report in this case?</p> <p>7 A. I did.</p> <p>8 Q. Did you read his supplemental report?</p> <p>9 A. Yes, I -- I did. I believe I --</p> <p>10 Q. And you are aware that Dr. Kimmel found some</p> <p>11 irregularities in the data reported by Dr. McGwin;</p> <p>12 correct?</p> <p>13 A. He referred to that. I didn't go into the</p> <p>14 details. Again, I'm not a statistician.</p> <p>15 Q. Well, were you aware that Dr. Kimmel --</p> <p>16 MR. OVERHOLTZ: I'm going to object. Try to</p> <p>17 let the witness finish answering the question.</p> <p>18 SPECIAL MASTER BORG: Fair enough. Were you</p> <p>19 finished, Doctor?</p> <p>20 THE WITNESS: Yeah, I'm not an expert, Ms.</p> <p>21 Leskin, in statistics and statistical methodology,</p> <p>22 but this is -- I trained in England. I did a</p> <p>23 fellowship at Moorefield's. The British Journal of</p> <p>24 Ophthalmology is a superb journal with a superb</p> <p>25 editorial board. And the methodology of Dr. McGwin</p> |
| <p style="text-align: right;">107</p> <p>1 A. Yes.</p> <p>2 Q. And that, in fact, would be a strength, in your</p> <p>3 mind, of this article, wouldn't it be?</p> <p>4 A. Yes.</p> <p>5 Q. I want you to assume hypothetically that the</p> <p>6 authors did not count exposed cases as represented in</p> <p>7 the article, but they also counted as exposed cases</p> <p>8 people who were diagnosed with NAION before they ever</p> <p>9 took Viagra. Would that make these findings</p> <p>10 unreliable?</p> <p>11 MR. BECNEL: Objection.</p> <p>12 MR. OVERHOLTZ: Object to form. Lack of</p> <p>13 foundation.</p> <p>14 MS. LESKIN: It's a hypothetical.</p> <p>15 MR. OVERHOLTZ: It's an improper hypothetical.</p> <p>16 SPECIAL MASTER BORG: More foundation would be</p> <p>17 helpful.</p> <p>18 BY MS. LESKIN:</p> <p>19 Q. Did you read the deposition of Dr. McGwin?</p> <p>20 A. You asked me that.</p> <p>21 Q. Okay. And you --</p> <p>22 A. The answer is no.</p> <p>23 Q. Did anyone tell you what Dr. McGwin testified</p> <p>24 to at his deposition on December 11th?</p> <p>25 A. I don't believe I specifically talked about Dr.</p> | <p style="text-align: right;">109</p> <p>1 and co-authors no doubt was reviewed. And it was</p> <p>2 probably the only study at that time. Was it</p> <p>3 perfect? No. Was it good study? Yes. It's so</p> <p>4 good that I believe that Pfizer has been negotiating</p> <p>5 with the FDA to basically do an expanded study based</p> <p>6 on his methodology for about three years now to put</p> <p>7 it together. But I'm sure it would be a difficult</p> <p>8 study because of the large numbers involved.</p> <p>9 But I can't cite chapter and verse as to who he</p> <p>10 called and what he called and which one number and</p> <p>11 what -- what reporting he did on each of these</p> <p>12 things.</p> <p>13 This study in general is a good study. Is it</p> <p>14 the best study out there? I don't know of any</p> <p>15 others that have good epidemiology, unfortunately.</p> <p>16 But we need to go with what we can conclude based on</p> <p>17 this.</p> <p>18 I think his conclusions regarding myocardial</p> <p>19 infarction and hypertension are valid and give you</p> <p>20 strong evidence to look further into why people</p> <p>21 develop NAION within 12 or 24 or 6 hours after</p> <p>22 taking this drug.</p> <p>23 MS. LESKIN: Objection; non-responsive.</p> <p>24 SPECIAL MASTER BORG: Sustained.</p> <p>25 BY MS. LESKIN:</p> |

28 (Pages 106 to 109)

| | |
|---|---|
| <p style="text-align: right;">110</p> <p>1 Q. Did you read the report of Dr. Kimmel, Doctor?</p> <p>2 A. I did.</p> <p>3 Q. And were aware that Dr. Kimmel found some</p> <p>4 irregularities in the data that Dr. McGwin used in</p> <p>5 calculating his -- his paper here?</p> <p>6 A. Yes. And that --</p> <p>7 MR. OVERHOLTZ: Object to -- Objection; lack of</p> <p>8 foundation --</p> <p>9 SPECIAL MASTER BORG: Overruled.</p> <p>10 MR. OVERHOLTZ: -- that Dr. Kimmel found</p> <p>11 anything. He reported finding some things.</p> <p>12 THE WITNESS: I just want to --</p> <p>13 SPECIAL MASTER BORG: Hang on, Doctor.</p> <p>14 THE WITNESS: I'm sorry.</p> <p>15 SPECIAL MASTER BORG: That's okay.</p> <p>16 All right. That sounds like a clarification.</p> <p>17 Is that -- Do you want to rephrase the question, Ms.</p> <p>18 Leskin?</p> <p>19 MS. LESKIN: I'll rephrase. I'll rephrase.</p> <p>20 BY MS. LESKIN:</p> <p>21 Q. Are you aware that Dr. Kimmel reported that he</p> <p>22 found what looks to be errors in the data used by Dr.</p> <p>23 McGwin in reaching his calculations as published in the</p> <p>24 British Journal of Ophthalmology?</p> <p>25 A. I believe he found some issues. I don't</p> | <p style="text-align: right;">112</p> <p>1 answer.</p> <p>2 SPECIAL MASTER BORG: And I'll -- That's</p> <p>3 overruled. And I will let him answer it, if he's</p> <p>4 able.</p> <p>5 MR. HOPPER: Do you understand the question?</p> <p>6 THE WITNESS: Yeah, if that were to happen,</p> <p>7 please -- it might alter my opinion, but please show</p> <p>8 me the letter.</p> <p>9 May --</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. If you assume hypothetically that Dr. McGwin</p> <p>12 and his colleagues did not count exposed cases as</p> <p>13 represented in the article -- I want you to assume that</p> <p>14 with me -- but that they counted exposed cases, people</p> <p>15 who were diagnosed with NAION before they took Viagra,</p> <p>16 would that make the findings of the McGwin study</p> <p>17 unreliable?</p> <p>18 MR. OVERHOLTZ: Objection; lack of foundation.</p> <p>19 Also lack of clarification. Counted all exposed</p> <p>20 people? Some exposed people? One exposed person?</p> <p>21 Two exposed persons? When they were exposed? It's</p> <p>22 just -- an improper hypothetical.</p> <p>23 SPECIAL MASTER BORG: You know, that's really</p> <p>24 not an appropriate objection under the Court's order</p> <p>25 here. But I -- I think foundation would be helpful</p> |
| <p style="text-align: right;">111</p> <p>1 believe there's ever been a follow-up letter to the</p> <p>2 editor or retraction or The British Journal of</p> <p>3 Ophthalmology saying, "Gee, we're sorry we published</p> <p>4 this article. And Dr. Kimmel" I believe he's a -- he</p> <p>5 works for Pfizer -- correct -- "found problems."</p> <p>6 So I take more what's published and what's out</p> <p>7 there. And if there was a mistake, I'm sure the</p> <p>8 article would have been retracted or Dr. McGwin would</p> <p>9 say, "We've made an error." I -- I haven't seen one.</p> <p>10 MS. LESKIN: Objection; non-responsive.</p> <p>11 SPECIAL MASTER BORG: Sustained.</p> <p>12 BY MS. LESKIN:</p> <p>13 Q. Are you aware that Dr. Kimmel reported that he</p> <p>14 found what looks to be errors in the data that Dr.</p> <p>15 McGwin used in calculating the numbers as published in</p> <p>16 The British Journal of Ophthalmology?</p> <p>17 A. I don't remember seeing those specifics. I</p> <p>18 would have to review Dr. Kimmel's deposition or report.</p> <p>19 If you want me, I would be happy to look at it with</p> <p>20 you.</p> <p>21 Q. If the University of Alabama were to write a</p> <p>22 letter to The British Journal of Ophthalmology</p> <p>23 withdrawing the article, would that change your opinion</p> <p>24 in this case?</p> <p>25 MR. HOPPER: Objection; calls for a speculative</p> | <p style="text-align: right;">113</p> <p>1 for that question to be answered. So, Ms. Leskin --</p> <p>2 MR. HOPPER: I will enter a follow-up objection</p> <p>3 as to form, and then it will be.</p> <p>4 SPECIAL MASTER BORG: Well, that doesn't get</p> <p>5 you there either.</p> <p>6 MR. HOPPER: Well, what will?</p> <p>7 SPECIAL MASTER BORG: Well --</p> <p>8 THE WITNESS: Well, let me answer.</p> <p>9 MR. HOPPER: Because it seems like we can't</p> <p>10 make any objection.</p> <p>11 SPECIAL MASTER BORG: No. No, no, no. You're</p> <p>12 not going to enter -- You know, I've -- I've said</p> <p>13 more foundation. Ms. Leskin, get some more</p> <p>14 foundation.</p> <p>15 You don't have three lawyers objecting. You</p> <p>16 get two. Pick your two.</p> <p>17 THE WITNESS: Can I -- I'm sorry -- was --</p> <p>18 was -- Is there still a question, Judge?</p> <p>19 SPECIAL MASTER BORG: No, nothing to you.</p> <p>20 THE WITNESS: Thank you.</p> <p>21 MR. HOPPER: Thank you, Judge.</p> <p>22 MS. LESKIN: We're going to look for some stuff</p> <p>23 that will help lay the foundation, and we will come</p> <p>24 back to it later.</p> <p>25 SPECIAL MASTER BORG: All right. Oh, all</p> |

29 (Pages 110 to 113)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|---|---|
| <p style="text-align: right;">114</p> <p>1 right. How are we doing on time, Mr. Videographer?</p> <p>2 THE VIDEOGRAPHER: We have 13 minutes left to</p> <p>3 tape change.</p> <p>4 SPECIAL MASTER BORG: Okay.</p> <p>5 BY MS. LESKIN:</p> <p>6 Q. Other than Dr. McGwin's article, Doctor, you</p> <p>7 identified some case reports as part of the evidence</p> <p>8 that you considered in determining whether Viagra can</p> <p>9 cause NAION; correct?</p> <p>10 A. Yes.</p> <p>11 Q. Is it your opinion that case reports can</p> <p>12 establish causation?</p> <p>13 A. No. But they need one to make a decision. For</p> <p>14 instance, the McGwin report. If Dr. McGwin had never</p> <p>15 written this or decided to study something else and</p> <p>16 never got interested in Viagra, in this situation,</p> <p>17 based on all the facts here, let's just exclude Dr.</p> <p>18 McGwin, although it's tantalizing, I would still reach</p> <p>19 the same conclusions, because I think the conclusions</p> <p>20 here are -- are limited. But you asked me everything</p> <p>21 that I used to base my report and that's why I</p> <p>22 mentioned Dr. Gwin -- McGwin.</p> <p>23 Q. Okay. So --</p> <p>24 A. But -- u-m-m ...</p> <p>25 Q. Other than Dr. McGwin --</p> | <p style="text-align: right;">116</p> <p>1 reports of visual loss using Viagra, as I mentioned the</p> <p>2 one in the child. There are cases of stroke and other</p> <p>3 issues following Viagra. I didn't pay that much</p> <p>4 attention to those. I try to limit it to the eye. But</p> <p>5 there's a series of case reports and --</p> <p>6 Q. And are you considering cases other than NAION</p> <p>7 in reaching that opinion?</p> <p>8 A. For this particular report, I just was</p> <p>9 restricted to NAION, because that was the issues with</p> <p>10 Mr. Stanley and Mr. Martin. I think when we look at</p> <p>11 the overall disease and mechanisms, you have to look if</p> <p>12 someone swallows Viagra and six hours later has a TIA,</p> <p>13 I think you have to look at that and look at the</p> <p>14 mechanisms and does that mechanism help explain the</p> <p>15 overall knowledge of what happens with the drug, and</p> <p>16 the answer may be yes. But I sort of limited myself</p> <p>17 for the most part to the -- to NAION.</p> <p>18 Q. If a patient takes a -- takes Viagra and six</p> <p>19 hours later has a TIA, does that mean that the Viagra</p> <p>20 caused the TIA?</p> <p>21 A. Not necessarily. I think you'd have to look</p> <p>22 specifically at the circumstances involved.</p> <p>23 Q. Well, would you have to look to see whether men</p> <p>24 who take Viagra have a higher rate of stroke as opposed</p> <p>25 to men who don't take Viagra?</p> |
| <p style="text-align: right;">115</p> <p>1 A. I believe there are 60, 70 case reports. I</p> <p>2 haven't been -- you know -- I don't know how many have</p> <p>3 been published to -- to date. There have been a lot of</p> <p>4 cases. Any individual case report adds to helping us</p> <p>5 make the conclusion. But case reports, I agree, if you</p> <p>6 -- if that's what you're suggesting, are not the</p> <p>7 strongest piece of evidence. They're part of the</p> <p>8 evidence.</p> <p>9 Q. You just told me there are 60 to 70 case</p> <p>10 reports. Have you ever listed those case reports?</p> <p>11 A. No, I don't.</p> <p>12 Q. What's the basis for your knowledge that</p> <p>13 there's 60 to 70 case reports out there?</p> <p>14 A. I believe in the FDA database, the last --</p> <p>15 someone -- one of the reports from one of the experts</p> <p>16 here said there were in the fifty-something range. And</p> <p>17 I tried to access that, but I don't have the raw data</p> <p>18 from the FDA database.</p> <p>19 Q. Okay. So you're being -- adverse event</p> <p>20 reports? You're not referring to published case</p> <p>21 reports; correct?</p> <p>22 A. Yeah, I mean, I think there are pro -- I'm</p> <p>23 sorry -- I may have misspoke. I think there are</p> <p>24 probably -- in published, there are 15, 20, 25. I mean</p> <p>25 there's case reports, not all in men. There are case</p> | <p style="text-align: right;">117</p> <p>1 A. That would be one of the things you'd have to</p> <p>2 look at, yes.</p> <p>3 Q. Are you aware of any evidence that men who take</p> <p>4 Viagra have a higher rate of stroke than men who don't</p> <p>5 take Viagra?</p> <p>6 A. I didn't look into the evidence, so I'm not</p> <p>7 aware -- I did see several case reports of TIA</p> <p>8 following sildenafil use, yes.</p> <p>9 Q. Are you aware of any studies demonstrating that</p> <p>10 men who take Viagra have a higher rate of TIA following</p> <p>11 use?</p> <p>12 A. No.</p> <p>13 Q. In your report, I want to turn to -- I'm</p> <p>14 looking specifically at the Stanley report for now.</p> <p>15 A. Okay.</p> <p>16 Q. Looking at the third page of that report. And</p> <p>17 you refer to the most recent summary of well-accepted</p> <p>18 medical literature was recently published as a</p> <p>19 peer-reviewed editorial in the prestigious British</p> <p>20 Journal of Ophthalmology. Is that Dr. Hayreh's</p> <p>21 editorial?</p> <p>22 A. Yes.</p> <p>23 Q. Now I will mark as Exhibit 8 --</p> <p>24 (Sher Exhibit No. 8, four-page editorial</p> <p>25 entitled Non-arteritic anterior ischaemic optic</p> |

30 (Pages 114 to 117)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|---|--|
| <p style="text-align: right;">118</p> <p>1 neuropathy and phosphodiesterase-5 inhibitors by 2 Sohan Singh Hayreh, was marked for identification.) 3 BY MS. LESKIN: 4 Q. I'm going to cover up the correspondence on the 5 bottom. All right. 6 A. Okay. 7 Q. I've marked as Exhibit 8 an editorial by Sohan 8 Singh Hayreh published December 2008, British Journal 9 of Ophthalmology. And that's the article you're 10 referring to? 11 A. Yes, it is. 12 Q. If you can turn to the next-to-the-last page 13 with 1579 on the bottom. 14 A. Yes. 15 Q. At the end of the article, do you see where Dr. 16 Hayreh wrote "Competing interests: None"? 17 A. Yes. 18 Q. Did you know that Dr. Hayreh was a paid expert 19 in this litigation? 20 A. I suspect he didn't work for free. I wouldn't 21 be surprised. 22 Q. And you know that he worked for the plaintiffs 23 of this litigation; correct? 24 A. I think he does work for the plaintiffs in this 25 litigation.</p> | <p style="text-align: right;">120</p> <p>1 question, Ms. Leskin. 2 BY MS. LESKIN: 3 Q. Okay. You're aware that Dr. Hayreh's opinion 4 that Viagra can cause NAION was excluded in this case; 5 correct? 6 A. I didn't read the specific issues in terms of 7 what the Court -- in terms of the legal -- the 8 legalities of what Dr. Hayreh's opinion can be 9 presented or not. But Dr. Hayreh's opinions are here. 10 It's published in a peer review. And these are the 11 opinions that mattered to me in terms of me reaching my 12 judgment, not what a judge -- no offense -- says or 13 not, because that's based on legalities that I 14 don't understand. 15 Q. Okay. 16 SPECIAL MASTER BORG: It's okay. I wasn't the 17 judge in that, so it doesn't matter. 18 THE VIDEOGRAPHER: We have three minutes to 19 tape change, Ms. Leskin. 20 SPECIAL MASTER BORG: Okay. 21 MS. LESKIN: Okay. 22 SPECIAL MASTER BORG: How much time? 23 THE VIDEOGRAPHER: Three minutes. 24 SPECIAL MASTER BORG: Okay. Well, let's just 25 take it here.</p> |
| <p style="text-align: right;">119</p> <p>1 Q. Now Dr. Hayreh's article is not a clinical 2 study; correct? 3 A. No. It's an editorial. 4 Q. That just means it's his opinion; correct? 5 Correct? 6 A. Yes. 7 Q. And are you aware that, and I think we talked 8 about this, Dr. Hayreh gave an opinion in this 9 litigation; correct? 10 A. Yes. 11 Q. And the opinion he gave in this litigation 12 included, among other things, that Viagra can cause 13 NAION; correct? 14 A. Yes. 15 Q. And you're aware that his opinion was excluded 16 by the Court; right? 17 MR. HOPPER: Objection. 18 THE WITNESS: Well -- 19 MR. HOPPER: Objection. 20 THE WITNESS: I'm sorry. I -- I can't answer. 21 MR. HOPPER: Mischaracterizes the record in 22 this case. His opinion was not excluded in this 23 case. Portions of his opinions were. And he was 24 left to stand as an expert in this case on Daubert. 25 SPECIAL MASTER BORG: Okay. Let's clean up the</p> | <p style="text-align: right;">121</p> <p>1 MS. LESKIN: Okay. 2 SPECIAL MASTER BORG: Okay. 3 MR. HOPPER: Yeah. 4 THE VIDEOGRAPHER: For identification, this is 5 the end of Videotape 1. The time is 10:57 a.m. 6 SPECIAL MASTER BORG: Let's take ten minutes. 7 (A short break was held from 10:57 a.m. to 8 11:16 a.m.) 9 THE VIDEOGRAPHER: For identification, this is 10 the beginning of Videotape 2. The time is 11:17 11 a.m. We are now back on the video record. 12 BY MS. LESKIN: 13 Q. Doctor, before the break, we were discussing 14 Dr. Hayreh's article that we've marked as Exhibit 8. 15 A. Yes. 16 Q. His 2008 editorial in The British Journal of 17 Ophthalmology. On Page 3 of your report in the Stanley 18 case, and actually also on Page 3 of your report in the 19 Martin case, you summarize three basic points that you 20 took away from this editorial; is that a fair 21 description of those three points? 22 A. Yes. 23 Q. Okay. So I would like to go through those with 24 you. The first one says, "A temporal relationship 25 between the ingestion of the drug and the onset of</p> |

31 (Pages 118 to 121)

| | |
|---|---|
| <p style="text-align: right;">122</p> <p>1 NAION."</p> <p>2 What's your understanding of what Dr. Hayreh</p> <p>3 says about the temporal relationships between the</p> <p>4 ingestion of the drug and the onset of NAION?</p> <p>5 A. In Dr. Hayreh's articles, his basic hypothesis</p> <p>6 is -- is that there is a drop in blood pressure</p> <p>7 particularly at night in many patients. He feels that</p> <p>8 the drug frequently is used -- well, in this case,</p> <p>9 specifically, it's the drug is used within 24 or</p> <p>10 possibly 36 hours before the use -- before the onset of</p> <p>11 symptoms. Usually, most people say there are five</p> <p>12 half-lives of the drugs, so 24 hours is -- is usually</p> <p>13 the extent when the drug is -- is having its action.</p> <p>14 He says that in these cases, the drug is used before</p> <p>15 the onset of the symptoms. That's all I'm summarizing</p> <p>16 in that sentence.</p> <p>17 Q. Well, in fact, if you look at Page 1578 of his</p> <p>18 article, which is Exhibit 8, on the left-hand column,</p> <p>19 there's the third arrow.</p> <p>20 A. Yes.</p> <p>21 Q. And he says, "Like the vast majority of NA-AION</p> <p>22 patients, most of the reported cases of NA-AION</p> <p>23 following ingestion of Viagra discovered visual loss</p> <p>24 upon awakening in the morning." Do you see that?</p> <p>25 A. Yes.</p> | <p style="text-align: right;">124</p> <p>1 Q. Okay. And you're not relying on the fact that</p> <p>2 people woke up with NAION after they used the drug, but</p> <p>3 simply that they took the drug and then developed</p> <p>4 NAION; is -- is that a fair distinction?</p> <p>5 MR. HOPPER: Objection; vague. You're</p> <p>6 referring to people. I don't know what you mean.</p> <p>7 MS. LESKIN: I'm trying to use his language.</p> <p>8 MR. HOPPER: Okay.</p> <p>9 MS. LESKIN: I'm trying to understand his</p> <p>10 opinion.</p> <p>11 MR. HOPPER: His opinion is for Mr. Stanley</p> <p>12 here, I believe, you are talking about.</p> <p>13 MS. LESKIN: Well, I'm talking more general</p> <p>14 than Mr. Stanley.</p> <p>15 MR. HOPPER: Okay. Then you should maybe</p> <p>16 rephrase.</p> <p>17 MS. LESKIN: Well, did you understand the</p> <p>18 question, Doctor?</p> <p>19 THE WITNESS: If we -- I'm -- I'm a little</p> <p>20 confused about your question.</p> <p>21 BY MS. LESKIN:</p> <p>22 Q. Okay. So let me -- let me strike that</p> <p>23 question. I'll ask -- I'll ask it again. I'll try</p> <p>24 again.</p> <p>25 Dr. Hayreh, in his article, writes, "The</p> |
| <p style="text-align: right;">123</p> <p>1 Q. Is that the temporal relationship you're</p> <p>2 referring to?</p> <p>3 A. No.</p> <p>4 Q. Okay. What temporal relationship between</p> <p>5 Viagra use and the onset of NAION are you referring to</p> <p>6 in this article?</p> <p>7 A. Well, and -- and it -- it is. My sentence here</p> <p>8 is basically that patients had to ingest the drug,</p> <p>9 somewhat what your question was before. We're not</p> <p>10 talking about cases where people weren't using the</p> <p>11 drug.</p> <p>12 And Dr. Hayreh, who aptly describes in his</p> <p>13 extensive work on this disease that most cases of NAION</p> <p>14 seem to appear in the morning, which is -- goes</p> <p>15 together nicely with his ideas that the drug -- and</p> <p>16 that -- excuse me -- that hypotension at night, a drop</p> <p>17 in blood pressure at night causes this cascade of</p> <p>18 events that lead to this horrible problem in the optic</p> <p>19 nerve.</p> <p>20 Q. So, but your reliance on the temporal</p> <p>21 relationship is solely that the person took the drug</p> <p>22 before they had the onset of NAION; is that a --</p> <p>23 A. That's correct.</p> <p>24 Q. -- fair summary of your opinion?</p> <p>25 A. That's a fair summary.</p> | <p style="text-align: right;">125</p> <p>1 majo -- Like the vast majority of NA-AION patients,</p> <p>2 most of the reported cases of NA-AION following</p> <p>3 ingestion of Viagra discovered visual loss upon</p> <p>4 awakening in the morning."</p> <p>5 And I just want to understand that your take</p> <p>6 away of the temporal relationship from Hayreh is not</p> <p>7 this specific temporal relationship about waking up in</p> <p>8 the morning?</p> <p>9 A. No.</p> <p>10 Q. It's solely that the person took a drug and</p> <p>11 then developed NAION; is that fair?</p> <p>12 A. Correct. That's -- that's true.</p> <p>13 Q. And is the fact --</p> <p>14 MR. HOPPER: Thank you, Counsel.</p> <p>15 BY MS. LESKIN:</p> <p>16 Q. And the fact that the person took the drug and</p> <p>17 developed NAION, is that evidence in your mind that the</p> <p>18 drug caused the NAION?</p> <p>19 A. It's one of the factors. It's not all the</p> <p>20 evidence.</p> <p>21 Q. Okay.</p> <p>22 A. Again, you're -- it's -- it's a complex answer.</p> <p>23 Q. Okay. So that's not the only basis?</p> <p>24 A. It is not.</p> <p>25 Q. Okay. But that when you say temporal</p> |

32 (Pages 122 to 125)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|--|--|
| <p style="text-align: right;">126</p> <p>1 relationship, that's what you're referring to?</p> <p>2 A. Right.</p> <p>3 Q. Okay. The number two take away you have from</p> <p>4 Dr. Hayreh's article is the presence of predisposing</p> <p>5 risk factors such as small vessel disease resulting in</p> <p>6 hypertension and heart disease and ED; right?</p> <p>7 A. Are you reading from --</p> <p>8 Q. No. 2 on --</p> <p>9 A. Oh, from --</p> <p>10 Q. -- Page 3 of your Stanley or Martin report?</p> <p>11 A. Oh -- Yes. I'm sorry. Yes.</p> <p>12 Q. Okay. What does Dr. Hayreh say about the</p> <p>13 presence of predisposing risk factors such as small</p> <p>14 vessel disease resulting in hypertension and heart</p> <p>15 disease and ED?</p> <p>16 A. "Most reported patients are middle-aged or</p> <p>17 elderly men." I'm reading from Page 1578.</p> <p>18 Q. Okay.</p> <p>19 A. "Arterial hypertension, diabetes,</p> <p>20 hyperlipidemia, and other systemic cardiovascular risk</p> <p>21 factors are common in this group. As discussed above,</p> <p>22 those factors predispose them to" he -- he calls NAION</p> <p>23 slightly different, but for -- I'll just say, "NAION."</p> <p>24 Q. He's actually very offended by calling it NAION</p> <p>25 and not non-arteritic anterior ischemic optic</p> | <p style="text-align: right;">128</p> <p>1 patients who take Viagra and get NAION; correct?</p> <p>2 A. It -- it's a generally fair statement. I would</p> <p>3 agree with that.</p> <p>4 Q. And you -- I think you said earlier that that</p> <p>5 was a typical presentation for men with NAION even</p> <p>6 before Viagra came on the market?</p> <p>7 A. Right. People get E -- men get ED because of</p> <p>8 problems in blood vessels and such. And these</p> <p>9 disposing factors cause ED, and they cause NAION,</p> <p>10 correct.</p> <p>11 Q. And, in fact, in your report, you wrote that</p> <p>12 experts in cardiovascular medicine teach that ED is one</p> <p>13 of the early signs of small blood vessel disease that</p> <p>14 can precede the symptoms of cardiovascular disease by</p> <p>15 several years?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay. The third take away you have from Dr.</p> <p>18 Hayreh's article that you mention in your reports is</p> <p>19 possible hypotension, systemic and hypotensive episodes</p> <p>20 localized to the optic nerve, from the combined use of</p> <p>21 the PDE-5 inhibitors, alpha and beta blockers. This</p> <p>22 can usually occur at night or usually can occur at</p> <p>23 night; right?</p> <p>24 A. Right.</p> <p>25 Q. Now where -- where does Dr. Hayreh talk about</p> |
| <p style="text-align: right;">127</p> <p>1 neuropathy, but --</p> <p>2 MR. HOPPER: Objection; Counsel is testifying.</p> <p>3 MS. LESKIN: Just making conversation.</p> <p>4 MR. HOPPER: I can't get sustained on that, can</p> <p>5 I?</p> <p>6 THE WITNESS: I would -- I would agree.</p> <p>7 SPECIAL MASTER BORG: I don't know that it was</p> <p>8 question.</p> <p>9 MR. HOPPER: It wasn't. That's why I'm saying</p> <p>10 she was testifying.</p> <p>11 BY MS. LESKIN:</p> <p>12 Q. You understand that that's Dr. Hay -- that's</p> <p>13 Dr. Hayreh's view?</p> <p>14 A. Yes.</p> <p>15 Q. And you -- you were reading --</p> <p>16 MR. HOPPER: There's the question we were</p> <p>17 looking for.</p> <p>18 BY MS. LESKIN:</p> <p>19 Q. You were reading from the left-hand column,</p> <p>20 that first triangle bullet point; correct?</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p> <p>23 A. 1578.</p> <p>24 Q. Right. And that statement, that's true, as Dr.</p> <p>25 Hayreh says, for all patients who get NAION, not just</p> | <p style="text-align: right;">129</p> <p>1 that?</p> <p>2 A. In --</p> <p>3 MR. HOPPER: Lori, excuse me. Where were you</p> <p>4 just reading from?</p> <p>5 MS. LESKIN: I was reading from No. 3 on Page 3</p> <p>6 of the report.</p> <p>7 MR. HOPPER: Thanks. Yeah. Okay.</p> <p>8 THE WITNESS: I think in general, and I was</p> <p>9 trying to tie this in to Mr. Stanley, because this</p> <p>10 is case-specific. Dr. Hayreh on that same page</p> <p>11 talks about invariably men with hypertension are</p> <p>12 variably -- excuse me -- invariably prescribed</p> <p>13 beta-blockers, ACE-inhibitor calcium channel</p> <p>14 blockers and other drugs with an arterial</p> <p>15 hypotensive effect.</p> <p>16 BY MS. LESKIN:</p> <p>17 Q. Okay. And that's, you're -- Just to be clear</p> <p>18 for the record, you're on Page 1578 --</p> <p>19 A. Yes.</p> <p>20 Q. -- middle column, second bullet; right?</p> <p>21 A. Yes, ma'am.</p> <p>22 Q. Okay. And, again, those are patients who are</p> <p>23 at risk for NAION even if they don't take Viagra;</p> <p>24 correct?</p> <p>25 A. Yes.</p> |

33 (Pages 126 to 129)

130

1 Q. Are you relying on Dr. Herey -- Dr. Hayreh's
2 theory of nocturnal hypotension for your opinion in
3 this case?

4 A. It's a fact, it's not a theory, that people
5 have hypotension at night, and it's one of the facts
6 that I'm relying on, because it best explains what
7 happens here. And nocturnal hypotension sets off this
8 cascade, this -- I think I used the term before -- "the
9 domino effect." And that could be -- That's sort of
10 the first domino.

11 Why is it that these people -- What happens to
12 them at night that starts this cascade, this -- this
13 terrible series of events that leads to the death of
14 their optic nerve? And arterial hypotension is
15 reasonable, it's proven, and it's logical.

16 Q. Now when you say it's proven, the fact that men
17 -- Well, strike that -- The fact that people have a
18 drop in blood pressure overnight while sleeping, that's
19 a proven fact; correct?

20 A. It is. And it's not just men. It's women,
21 too.

22 Q. Right. And that happens in pretty much
23 everybody?

24 A. To some degree, yes.

25 Q. Okay. And that's irrespective of medications

131

1 that they may or may not be taking; correct?

2 A. Yes. It's potentiated by certain medications,
3 but it generally happens to all of us to some degree.

4 Q. Are you aware of any clinical studies or
5 epidemiological studies that demonstrate that people
6 taking antihypertensive medications are at an increased
7 risk of NAION as opposed to patients who don't take
8 antihypertensive medications?

9 A. To save a long discussion that we had before
10 when Mr. Overholtz was objecting, there are no good
11 clinical studies for the reasons before to say that we
12 don't have the large numbers to prove NAION. NAION's a
13 relatively rare disease. So it -- Basically, it would
14 be my same answer. There's no particular studies with
15 hypotens -- you know -- hypotensive drugs -- you
16 know -- antihypertensive drugs to show that it's
17 necessarily related to NAION or not.

18 Q. Okay. But -- but that's clinical studies. So
19 let me -- I think I was asking about epidemiological
20 studies. Are you aware of any epidemiological studies
21 that show that men who take antihypertensive
22 medications are at an increased risk of NAION?

23 A. I don't know the answer to that. It's common
24 knowledge that men with NAION have hypertension.
25 Hypertension is common in the population. I think a

132

1 third to a half of all men over 50 have some. I can't
2 quote -- I didn't go into those studies in -- in
3 particular to -- to look, but there's certainly an
4 increased rate of NAION in people with hypertension
5 versus not hypertension.

6 Q. But that --

7 A. Doesn't prove anything here in terms of the --
8 the nitty-gritty of this, however.

9 Q. And it doesn't prove that it's the
10 antihypertensive medications -- correct -- that's
11 causing the NAION?

12 A. There are -- I don't -- I'm not aware of
13 adverse event reports, particularly with the FDA, for
14 any particular -- besides maybe an isolated report that
15 there's any NAION associated with particular
16 antihypertensive agents.

17 I looked particularly specifically for -- for
18 the alpha-blocker that -- the Catapres, particularly, I
19 looked up, and I couldn't find case reports of Catapres
20 causing NAION, and I couldn't find case reports of
21 Accupril, another medication Mr. Martin was on, causing
22 NAION. They may be out there, but it's certainly
23 nowhere near the number of adverse event reports for
24 NAION that -- that have been associated with ED drugs.

25 Q. Are you aware --

133

1 THE VIDEOGRAPHER: If you will excuse me, Ms.
2 Leskin. That last question and answer, I'm getting
3 a lot of interference from a cell phone or a
4 Blackberry or something that may not be off totally.

5 THE WITNESS: I'm sorry. Mine's off.

6 THE VIDEOGRAPHER: They need to be totally off,
7 please. Thank you.

8 I could hear the answer, but you're going to
9 get a lot of static -- background noise in there.

10 THE WITNESS: Did you hear the answer? Can you
11 repeat it?

12 THE COURT REPORTER: Yes, I can.

13 THE WITNESS: I don't want to say it again.

14 SPECIAL MASTER BORG: We'll just read it back.

15 THE VIDEOGRAPHER: I've got it on record, but
16 it's -- there's a lot of static in the background.

17 SPECIAL MASTER BORG: I understand.

18 MR. HOPPER: That's all right. We have a
19 record.

20 SPECIAL MASTER BORG: Okay.

21 BY MS. LESKIN:

22 Q. Are you aware of any studies -- Well, strike
23 that.

24 Are you aware of any reports of nitrates
25 causing NAION or being associated with NAION?

34 (Pages 130 to 133)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|---|---|
| <p style="text-align: right;">134</p> <p>1 A. I didn't look specifically at nitrates. I'm --</p> <p>2 I'm aware of the strong warning that nitrates should</p> <p>3 not be used with PD-5 inhibitors.</p> <p>4 Q. Okay.</p> <p>5 A. I -- I didn't look specifically for that. So</p> <p>6 there may be. I just don't know.</p> <p>7 Q. You will agree with me that nitrates are a</p> <p>8 strong vasodilator; correct?</p> <p>9 A. Yes.</p> <p>10 Q. And nitrates result in drops in blood pressure?</p> <p>11 A. Sometimes, yes.</p> <p>12 Q. I want to go back to the -- the</p> <p>13 Levin/Danesh-Meyer Hypothesis article which we marked</p> <p>14 previously as Exhibit 6. And that's the article you</p> <p>15 cite next in your report; correct?</p> <p>16 A. Yes.</p> <p>17 Q. That's in that report underneath the bullet --</p> <p>18 the paragraph underneath the bullet points?</p> <p>19 MR. HOPPER: I'm sorry, Lori. I don't see our</p> <p>20 copy of that. It was here.</p> <p>21 MR. OVERHOLTZ: I took it when you were out.</p> <p>22 MR. HOPPER: Sure. Sorry, Lori.</p> <p>23 BY MS. LESKIN:</p> <p>24 Q. Now this article is labeled as a hypothesis;</p> <p>25 correct?</p> | <p style="text-align: right;">136</p> <p>1 involves money.</p> <p>2 Q. Well, do you agree that it's --</p> <p>3 A. I mean, it's con --</p> <p>4 Q. Do you agree that the existence of the</p> <p>5 association is controversial?</p> <p>6 A. I think there are opinions on -- on both sides</p> <p>7 to -- Not everybody agrees with the association. So I</p> <p>8 think that's a fair statement that -- that it is</p> <p>9 controversial, because some people believe it exists</p> <p>10 and some people believe that it may not exist.</p> <p>11 Q. Now the theory, the hypothesis that Drs. Levin</p> <p>12 and Danesh-Meyer put forth is that NAION is</p> <p>13 precipitated by venous insufficiency, with venous</p> <p>14 congestion causing initial disc edema; correct?</p> <p>15 A. In some cases. Dr. Levin is not trying to</p> <p>16 explain all NAION. He's just trying to explain some of</p> <p>17 the inconsistencies and have a better theory that would</p> <p>18 take into account some of the cases we see and some of</p> <p>19 the clinical findings we see when we examine our</p> <p>20 patients, yes, and --</p> <p>21 Q. I'm trying to understand what the underlying</p> <p>22 cause of NAION is to begin with.</p> <p>23 A. Yes.</p> <p>24 Q. Because some people, like Dr. Hayreh, believe</p> <p>25 in this nocturnal hypotension theory, but there are</p> |
| <p style="text-align: right;">135</p> <p>1 A. Yes.</p> <p>2 Q. And that -- And Drs. Levin and Danesh-Meyer</p> <p>3 recognize that this is a theory that deserves further</p> <p>4 investigation; correct?</p> <p>5 A. I think that's a fair statement, yes.</p> <p>6 Q. And if you look at Page 1582, which is that</p> <p>7 front page --</p> <p>8 A. Yes, I have it.</p> <p>9 Q. If you look at the top of the right-hand column</p> <p>10 after the foot -- that first footnote, it says, "There</p> <p>11 is some association with the use of phosphodiesterase-5</p> <p>12 inhibitor drugs for erectile dysfunction, although this</p> <p>13 is controversial." Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. That's a true statement; correct?</p> <p>16 A. I'm sure it's controversial. And there is some</p> <p>17 association -- there is some association -- some</p> <p>18 association. That's what he writes.</p> <p>19 Q. Okay. And do you agree with that sentence?</p> <p>20 A. Which sentence?</p> <p>21 Q. The sentence we just read.</p> <p>22 A. That there is an association?</p> <p>23 Q. That there is an --</p> <p>24 A. Yes -- Yes, I do. And that it's controversial,</p> <p>25 I would probably agree with that, too, because it</p> | <p style="text-align: right;">137</p> <p>1 others who disagree with that theory; correct?</p> <p>2 A. There are some, yes.</p> <p>3 Q. And what Drs. Levin and Danesh-Meyer are</p> <p>4 attempting to do is explain a potential other theory</p> <p>5 for the underlying cause of NAION; right?</p> <p>6 A. I -- I think that's correct. And I don't think</p> <p>7 they're mutually exclusive. I think it's just -- adds</p> <p>8 more facts to Dr. Hayreh's ideas. In -- in my opinion,</p> <p>9 it better explains what they see.</p> <p>10 Q. And that includes explaining why people with a</p> <p>11 disc at risk seem to have a greater incidence of NAION</p> <p>12 than people without that; right?</p> <p>13 A. Possibly, yes.</p> <p>14 Q. And a disc at risk is a tight opening from the</p> <p>15 eyeball back into the optic nerve; right?</p> <p>16 A. Yes. A smaller cup-disc ratio. So that's a</p> <p>17 good description.</p> <p>18 Q. And the theory, as I understand, from Drs.</p> <p>19 Levin and Danesh-Meyer is that when the inflam -- when</p> <p>20 the -- the vessels expand, it closes off drainage</p> <p>21 through the veins; correct?</p> <p>22 A. Yes. It -- it reduces it.</p> <p>23 Q. Now Drs. Levin and Danesh-Meyer identified this</p> <p>24 as a hypothesis. Are you aware of any testing that's</p> <p>25 been done to look at this hypothesis?</p> |

35 (Pages 134 to 137)

| | |
|---|--|
| <p style="text-align: right;">138</p> <p>1 A. Well, they -- they referred to some studies 2 and -- and such, but, again, it's a very difficult 3 thing to certainly test in humans. Most animal models 4 don't work. It's still a hypothesis, I think it's 5 fair. It's just a very elegant well-thought-out 6 explanation of some of the facts that don't go into the 7 overall theory of why we see some people with certain 8 types of swelling in the disc with hemorrhages versus 9 some people with very pale extravated discs that are 10 more arterial. And I think it explains possibly, 11 and -- and the reason I put it into my report, is it 12 better explains possibly why you have possibly 13 increased blood flow through the artery of -- the 14 essential retinal artery which goes through the optic 15 nerve and how that increase in a brittle nerve that's 16 tightly bound and a vein that collapses could collapse 17 the vein and set off this -- and I use the word 18 "cascade" again -- of events that -- that lead to this 19 disease. 20 And, to me, it explains some of the things that 21 we couldn't explain necessarily as well before from 22 just using Dr. Hayreh's and some -- others' arterial 23 hypotension insufficiency. I think it takes both. But 24 it does explain it better in my mind. 25 Q. But at this point in time, the -- this is still</p> | <p style="text-align: right;">140</p> <p>1 Q. And you ex -- you said that -- Well, as we 2 said, this is a potential theory as to the underlying 3 cause of NAION; right? 4 A. It is. 5 Q. And it's also a potential theory as to how 6 Viagra could possibly cause NAION; correct? 7 A. Yes. 8 Q. And that part of the theory hasn't been tested 9 either; right? 10 A. That's correct. 11 Q. Would this theory explain how other drugs could 12 potentially cause NAION? 13 A. Yes. It's a possibility in terms of -- of the 14 other ED drugs could cause NAION, because I think they 15 work through similar mechanisms, although they -- there 16 are certain differences. 17 Q. Would it explain how potentially other drugs 18 besides ED drugs could cause NAION? 19 MR. HOPPER: Objection; vague. 20 THE WITNESS: I'm sorry. 21 SPECIAL MASTER BORG: It's -- it's overruled. 22 I think he's able to answer it. 23 MR. HOPPER: "Other drugs"? I mean, that's as 24 vague as you can get. 25 MS. LESKIN: The objection has been overruled.</p> |
| <p style="text-align: right;">139</p> <p>1 a theory; correct? 2 A. It is a theory. I don't know what it would be 3 to take -- If you would ask me what would it take to 4 make this a fact, it's -- it would be difficult. It's 5 -- We knew for 50 years since the 1950s that cigarettes 6 cause cancer, but it may be only in 10 to 15 years to 7 really figure out how. So probably in 10, 15 years, 8 this -- people will come up with ways to figure this 9 out. Maybe -- maybe sooner, the way technology is 10 moving. 11 Q. And Drs. Levin and Danesh-Meyer set forth some 12 of the testable implications at the end of their 13 article -- correct -- to look at their hypothesis? 14 A. If you want to be more specific about any -- 15 any one of them? 16 Q. Well, they have a section called Testable 17 Implications; right? 18 A. Right. There were a number of things, so I 19 didn't want to comment on the whole -- the whole thing. 20 Q. Okay. And I actually wasn't asking for your 21 comments. 22 A. Okay. Sure. 23 Q. I was just asking if they set out some 24 potential ways that this theory could be tested; right? 25 A. Yes.</p> | <p style="text-align: right;">141</p> <p>1 SPECIAL MASTER BORG: It's -- it's overruled. 2 Can you answer the question, Doctor? Do you 3 understand it? 4 THE WITNESS: I think I understand the 5 question. 6 SPECIAL MASTER BORG: Okay. 7 THE WITNESS: I'm just not aware if we're 8 looking at vascular NAION, because it doesn't 9 explain why ethambutol might cause optic nerve 10 disease, but it certainly might explain why Levitra, 11 Cialis might cause it. And I haven't -- I'm not 12 aware of other drugs that have really conclusively 13 been associated with NAION other than the ED drugs. 14 BY MS. LESKIN: 15 Q. Okay. And there's been no testing for the 16 other ED drugs either under this theory; correct? 17 A. I haven't seen it in the article. And I didn't 18 look at the other drugs specifically to see. I just 19 didn't find any other articles about them. But I 20 didn't look -- I didn't -- I confined my analysis -- 21 there was a limited amount of time -- to -- to 22 sildenafil. 23 Q. You told me earlier that you spoke with Dr. 24 Levin this past week; right? 25 A. Yes.</p> |

36 (Pages 138 to 141)

| | |
|---|--|
| <p style="text-align: right;">142</p> <p>1 Q. What was the nature of that conversation?</p> <p>2 A. We hadn't met. He -- I called him, and I first</p> <p>3 indicated that I was giving a deposition, and I didn't</p> <p>4 want him to feel uncomfortable about saying anything,</p> <p>5 and that if there was a conflict that I wasn't aware</p> <p>6 about that he would be in. And I said that I read his</p> <p>7 editorial and that I felt it explained things that had</p> <p>8 been bothering me for 25 years about seeing these</p> <p>9 patients, because they just don't all fit into one</p> <p>10 category. And we have certain findings where some</p> <p>11 nerves initially are very pale, and I'm talking about</p> <p>12 initially. And other nerves have venous issues. And</p> <p>13 we're talking about why would a cup-disc ratio that's</p> <p>14 very tight necessarily -- excuse me -- a small cup-disc</p> <p>15 ratio. You -- you referred to it as something else.</p> <p>16 Q. Disc at risk?</p> <p>17 A. Yeah, disc at risk. I like that term.</p> <p>18 I asked him, one, if he would like to explain a</p> <p>19 little bit more about his theories to me. We talked</p> <p>20 for about 20 minutes. And I asked him if -- how his</p> <p>21 editorial was received, if there were a lot of people</p> <p>22 that wrote him or violently disagreed, and was there</p> <p>23 controversy, and he said, "No."</p> <p>24 I asked him what it would take to prove his</p> <p>25 theory, and he said they would have to build MRI</p> | <p style="text-align: right;">144</p> <p>1 patients, based on the totality here, so not one</p> <p>2 editorial or one particular epidemiologic study or</p> <p>3 anybody's written deposition or expert report really</p> <p>4 made me reach my conclusions.</p> <p>5 I looked, and particularly on the two</p> <p>6 individuals I was asked to examine and look at their</p> <p>7 records in detail, to reach that conclusion. And</p> <p>8 that's where my conclusion comes from.</p> <p>9 And -- and it's -- it's -- it's difficult for</p> <p>10 me, because sometimes people say, well, bring in all</p> <p>11 the documents you've read to reach your conclusion.</p> <p>12 Well, it's 30 years of what I do, which is practice</p> <p>13 medicine and see patients. I also have the benefit of</p> <p>14 understanding some drug studies. I've worked for the</p> <p>15 Food and Drug Administration when I was in the public</p> <p>16 health service for three years. I've -- I've reviewed</p> <p>17 drug applications in the allergenic and vaccine area --</p> <p>18 allergenic area -- excuse me. It was part of the</p> <p>19 vaccine portion. I have run clinical trials. And --</p> <p>20 and I think I have a good understanding of physiology</p> <p>21 and -- and the other disciplines that lead me to make</p> <p>22 that decision. If I didn't think it caused it, I</p> <p>23 wouldn't write it, and I guess I might not be here, but</p> <p>24 that was my opinion.</p> <p>25 MS. LESKIN: What was the question that I</p> |
| <p style="text-align: right;">143</p> <p>1 machines, and I think these are machines that are</p> <p>2 called Tesla. They are certain machines, the more</p> <p>3 Teslas -- you know -- to -- to look at nerves. The</p> <p>4 technology isn't there to prove his theory.</p> <p>5 And I asked him to explain the anatomy exactly</p> <p>6 how he studied it between the anat -- the artery and</p> <p>7 the vein and were they fully encased, and he explained</p> <p>8 that to me. That was about the extent of my</p> <p>9 conversation.</p> <p>10 Q. Did any of the conversation discuss</p> <p>11 specifically Viagra or the other ED medications?</p> <p>12 A. No. I -- I really wanted to go in the general</p> <p>13 mechanism, and I didn't want to pin him down to a</p> <p>14 discussion of that.</p> <p>15 Q. When we were talking earlier and you told me</p> <p>16 the basis for your opinion that Viagra -- Viagra is</p> <p>17 capable of causing NAION, you mentioned the</p> <p>18 epidemiological study by Dr. McGwin, the case reports</p> <p>19 which we've discussed, and editorials. The editorials</p> <p>20 that -- that you're referring to -- the editorial by</p> <p>21 Dr. Hayreh and the editorial by Dr. Levin?</p> <p>22 A. Well, among other descriptions. My -- my</p> <p>23 conclusions, Ms. Leskin, are based on having practiced</p> <p>24 medicine for -- since 1978 or 9, been a physician since</p> <p>25 I was 22, in 1971 when I graduated, seeing thousands of</p> | <p style="text-align: right;">145</p> <p>1 asked?</p> <p>2 (The requested portion of the record was read.)</p> <p>3 MS. LESKIN: Objection; non-responsive.</p> <p>4 SPECIAL MASTER BORG: Sustained.</p> <p>5 MR. BECNEL: Objection to the Court's ruling.</p> <p>6 Objection to the Special Master's ruling.</p> <p>7 BY MS. LESKIN:</p> <p>8 Q. Other than the editorials of Dr. Hayreh and Dr.</p> <p>9 Levin that we have been discussing, what other</p> <p>10 editorials were you referring to when you told me</p> <p>11 earlier that you were -- relied on editorials?</p> <p>12 A. I may have misspoke with the term "editorials"</p> <p>13 and was talking about in general articles. I don't</p> <p>14 have the specifics here.</p> <p>15 THE VIDEOGRAPHER: Excuse me, Mr. Hopper.</p> <p>16 MR. HOPPER: I apologize.</p> <p>17 BY MS. LESKIN:</p> <p>18 Q. Now you have mentioned several times today the</p> <p>19 totality of the evidence. And what I would like you to</p> <p>20 do before we talk about Mr. Stanley or Mr. Martin</p> <p>21 specifically --</p> <p>22 A. Mmm-hmm.</p> <p>23 Q. -- I'd like you to list for me all of the</p> <p>24 evidence that you're relying on, in addition to the</p> <p>25 McGwin study, the case reports, and the two editorials</p> |

37 (Pages 142 to 145)

146

1 that you identified, all of the evidence that you are
 2 bringing in for your opinion that Viagra is capable of
 3 causing NAION.
 4 MR. HOPPER: I'm going to enter an objection
 5 there as, first of all, asked and answered. And
 6 secondly, your Honor, she just asked him the
 7 question, and he gave her his honest answer, and now
 8 she wants to ask the question again. And she --
 9 she -- she -- she -- she's -- it's -- it's asked and
 10 answered, but she doesn't want to hear what he has
 11 to say because she's striking -- calling it
 12 non-responsive. So it -- it -- you know -- we're
 13 swimming between the devil and the deep blue sea
 14 here.
 15 SPECIAL MASTER BORG: I -- I understand the
 16 circular nature. I understand the --
 17 MR. HOPPER: It's tautological. Thank you.
 18 SPECIAL MASTER BORG: Well, I understand. I'm
 19 going to overrule it. He's already given the
 20 answer. It wasn't responsive, I would agree with
 21 that. But she's now asking the question that's
 22 going to get that answer. So she gets to do it.
 23 It's her time.
 24 MR. HOPPER: Well, it's -- it's her time,
 25 Judge, but it's -- it's -- it's -- there's --

147

1 there's -- there's -- there's fair game here. And
 2 it's certainly, out of respect to her, it's her
 3 deposition, but you can't ask a question and call it
 4 non-responsive and then come back and ask the same
 5 question again after he gave the answer and then
 6 expect that if he gives an answer, that's his honest
 7 answer, that because he's not giving the answer she
 8 wants, that that's not "the" answer.
 9 SPECIAL MASTER BORG: Okay. It's overruled.
 10 MR. HOPPER: Okay.
 11 SPECIAL MASTER BORG: Let's get the question
 12 back.
 13 MS. LESKIN: Can you read it --
 14 THE COURT REPORTER: How about if I start you
 15 off?
 16 SPECIAL MASTER BORG: Or do you just want to
 17 repeat it, Ms. Leskin?
 18 MS. LESKIN: Well, I want to see what -- It was
 19 a long question. So I'd like to --
 20 Okay. You know what? I'll -- I'll rephrase
 21 it.
 22 THE COURT REPORTER: Okay. Or you can read
 23 from here.
 24 MS. LESKIN: No. You know what. I'll -- I'll
 25 rephrase it. That's fine. I'll -- I'll make it a

148

1 little simpler.
 2 BY MS. LESKIN:
 3 Q. So far today, Doctor, we've talked about Dr.
 4 McGwin's epidemiological study. We've talked about
 5 case reports. We've talked about the editorials by Dr.
 6 Hayreh and Dr. Levin. In addition to those pieces of
 7 evidence, what other evidence are you relying on for
 8 your opinion that Viagra is capable of causing NAION?
 9 MR. HOPPER: Objection; asked and answered.
 10 SPECIAL MASTER BORG: Overruled. This asks for
 11 evidence. Go ahead, Doctor.
 12 THE WITNESS: May I answer, Judge?
 13 SPECIAL MASTER BORG: Yes.
 14 THE WITNESS: Ms. Leskin, I actually thought I
 15 said it pretty well, so if you have a cut-and-paste,
 16 you can put it in. But I'll just be brief with you.
 17 And I mean that, put it in the record. I think it
 18 was the same exact question, and I'll give the same
 19 exact answer. But I also want to say that I have
 20 read through -- I must admit I don't remember every
 21 detail. It's tougher when you get to my age --
 22 of -- of each of these reports.
 23 I also add that in the practice of medicine for
 24 30 years, ophthalmology for almost that amount of
 25 time, my clinical experience, my judgment as a

149

1 scientist. I think I'm a scientist, and -- and that
 2 I'm objective. And I bring all that to bear in my
 3 decision.
 4 Now you may -- You're a lawyer, and you think
 5 differently than me. And -- and a very good lawyer.
 6 But -- And so your thinking about this may be
 7 different. But I bring in, and as a physician,
 8 that's my opinion. And -- and if there's any
 9 specifics here that you want to ask me what I would
 10 agree to, if you would want to show me, I'm -- I'm
 11 happy to expand on that. But I think I've answered
 12 the question.
 13 MS. LESKIN: Can I -- I just want to see that
 14 for a second.
 15 THE COURT REPORTER: Sure.
 16 BY MS. LESKIN:
 17 Q. And -- and Doctor, I just really am trying to
 18 understand the basis of your opinion. That's all I'm
 19 trying to find out today.
 20 A. Sure.
 21 Q. And I just want to make sure I'm not missing
 22 something. So, again, I just -- We talked about
 23 McGwin. We talked about the case reports. We talked
 24 about Levin's article -- editorial in 2008. We talked
 25 about Hayreh's 2008 editorial. And now we've -- you've

38 (Pages 146 to 149)

| | |
|--|--|
| <p style="text-align: right;">150</p> <p>1 identified the items on the list that's Exhibit 2 and</p> <p>2 your experience as a physician.</p> <p>3 A. And the science.</p> <p>4 Q. Okay. When you say "the science" --</p> <p>5 A. The science, yes.</p> <p>6 Q. What do you mean by "the science"?</p> <p>7 A. The generally agreed upon idea, and it is among</p> <p>8 my colleagues, because Dr. Hayreh, who I respect and</p> <p>9 has written more and probably seen more cases than</p> <p>10 anybody in the world, and despite your pointing out</p> <p>11 that he was paid for his time, is probably one of the</p> <p>12 more independent and ornery people you will ever meet.</p> <p>13 And I respect Dr. Hayreh's opinion.</p> <p>14 And my basis -- my opinion -- and he</p> <p>15 beautifully points out the reasons for what causes this</p> <p>16 disease, what conditions might lead to it, and the</p> <p>17 associations, although it is a hypothesis; it's not a</p> <p>18 fact. Very few facts are here in terms of knowing for</p> <p>19 sure. This 99, 100 percent, medicine isn't that kind</p> <p>20 of science to explain what's going on.</p> <p>21 And when I look at Dr. Hayreh's theories, and I</p> <p>22 look at the other things that are written among many of</p> <p>23 these articles that I've pointed out, I look at the</p> <p>24 fact that one-third of the cases in the FDA database of</p> <p>25 NAION have ED drugs associated with them.</p> | <p style="text-align: right;">152</p> <p>1 And what Dr. Hayreh writes is so logical and</p> <p>2 explains this. And Dr. Hayreh has devoted his whole</p> <p>3 life, and I believe has not consulted for</p> <p>4 pharmaceutical companies. He's one of the few people</p> <p>5 in my field who are "experts" that have not. And he's</p> <p>6 a very independent guy. And I -- and I believe him.</p> <p>7 And I agree with him.</p> <p>8 Q. You made a statement that one-third of the</p> <p>9 NAION cases in the FDA database is associated with ED</p> <p>10 drugs.</p> <p>11 A. Yes, that was --</p> <p>12 Q. What's the basis for that statement?</p> <p>13 A. I believe I read it in a number of the expert</p> <p>14 reports. I just --</p> <p>15 Q. Which expert report?</p> <p>16 A. I'm sorry; I don't remember which one. Someone</p> <p>17 was talking about it in -- in one of their depositions.</p> <p>18 I'm sorry. I can't remember the name.</p> <p>19 Q. Do you have those with you?</p> <p>20 MR. HOPPER: Lori, when you said one-third of</p> <p>21 the basis, where are you referring to, please?</p> <p>22 MS. LESKIN: I'm referring to the statement he</p> <p>23 made in his deposition.</p> <p>24 MR. HOPPER: Oh, I'm sorry. I thought you were</p> <p>25 talking about in his report. I didn't remember it</p> |
| <p style="text-align: right;">151</p> <p>1 I look at what I think, and, again, I'm sorry</p> <p>2 to use the word "science," is there science or just --</p> <p>3 you know -- religious feeling about this? And I think</p> <p>4 there's science. It makes sense to me. It fits the</p> <p>5 descriptions.</p> <p>6 Dr. Levin's article adds a few more pieces to</p> <p>7 this puzzle. And in these cases and -- and some of the</p> <p>8 other cases no doubt, I feel that Viagra and the other</p> <p>9 related -- and Viagra is -- is related and caused this</p> <p>10 disease, that if these patients didn't take Viagra,</p> <p>11 they would probably most likely not have been blinded.</p> <p>12 Q. Okay.</p> <p>13 A. At least in case of the bilateral disease.</p> <p>14 Q. Now when you say that you respect Dr. Hayreh's</p> <p>15 theories, you haven't done any testing to test any of</p> <p>16 Dr. Hayreh's theories; correct?</p> <p>17 A. No.</p> <p>18 Q. Okay. You take him at his word from what he's</p> <p>19 written in his articles?</p> <p>20 A. I read his articles. I read his references.</p> <p>21 And I put that in the totality of what I know. And I</p> <p>22 say does this make sense, or is Dr. Hayreh or is Dr.</p> <p>23 Smith or Jones crazy and just coming out with some</p> <p>24 theory because God told him to in the middle of the</p> <p>25 night.</p> | <p style="text-align: right;">153</p> <p>1 being in his report.</p> <p>2 THE WITNESS: No, I'm sorry.</p> <p>3 MS. LESKIN: No. I didn't remember it being in</p> <p>4 his report either.</p> <p>5 MR. HOPPER: Okay.</p> <p>6 THE WITNESS: I tried to access this database</p> <p>7 because I thought it would be -- and it might have</p> <p>8 been Dr. Blume, but I -- I could be wrong.</p> <p>9 MS. LESKIN: Okay. Can you show me where --</p> <p>10 THE COURT REPORTER: Dr. -- Dr. Blume?</p> <p>11 MS. LESKIN: Blume -- B-L-U-M-E.</p> <p>12 MR. HOPPER: B-L-U-M-E.</p> <p>13 THE WITNESS: Yeah.</p> <p>14 BY MS. LESKIN:</p> <p>15 Q. Can you show me where in Dr. Blume's report?</p> <p>16 A. I didn't say that. I said I thought it might</p> <p>17 be and I'd have to go through -- I know I have read</p> <p>18 that, and it had been asserted to me, and I have no</p> <p>19 reason to disagree.</p> <p>20 I did try actually on the -- this week to</p> <p>21 access that, but the FDA database unfortunately came</p> <p>22 out as sort of gobbledygook. It just wouldn't open on</p> <p>23 my computer. And I didn't have time to look at it.</p> <p>24 And a lot of it is unfiltered, as -- as you know, but</p> <p>25 ...</p> |

39 (Pages 150 to 153)

154

1 Q. So when you say that -- well -- and -- and then
2 you are using this as a basis for your opinion, and I
3 want to know where you got that number from.

4 A. I can't give you the place. But if I'm wrong
5 and it's no cases reported, please show me. I'd be
6 happy to look at it. I just --

7 Q. Well, you've made a statement. I want to know
8 the basis for that statement.

9 A. I stand by the statement. I can't tell you
10 where I found it. It would probably -- I just don't
11 remember the specifics. And I've read a lot of
12 material you see --

13 Q. Is it something that a lawyer told you in this
14 case?

15 MR. HOPPER: Object; argumentative.

16 SPECIAL MASTER BORG: It is argumentative.
17 It's been asked three times. It's sustained.

18 MS. LESKIN: Whether a lawyer asked -- told him
19 this?

20 SPECIAL MASTER BORG: The answer has been, "I
21 don't know where I got it."

22 MS. LESKIN: Okay. If you remember, Doctor,
23 can you tell me today while we're here?

24 THE WITNESS: I will.

25 BY MS. LESKIN:

155

1 Q. Are you aware of any animal testing that's been
2 done as to whether Viagra can cause NAION?

3 A. The animal testing unfortunately -- There's --
4 there's been animal tests of Viagra, but unfortunately
5 almost all of the animal testing doesn't have much --
6 doesn't replicate the human model. Doesn't replicate
7 us.

8 Q. Have you reviewed the animal testing that's
9 been done by Pfizer of Viagra?

10 A. I have not.

11 Q. Do you know what was -- So do you know what
12 conclusions can or can't be drawn from that study if
13 you haven't reviewed it?

14 A. You'll have to ask me specific conclusions.

15 Q. Okay. Do you know if they found any evidence
16 of toxicity to any part of the visual pathway in any of
17 the animals that they tested?

18 A. I can't answer that directly. I don't -- If
19 you want to show me some data, I can answer that. I
20 did read a lot of blood flow studies in animals in the
21 eye in preparation to this. It was referred to, and I
22 tried to find those. I found those articles sort of
23 worthless.

24 MR. OVERHOLTZ: We'd make the same request and
25 objection. This is outside the scope of Dr. Sher's

156

1 report. If Ms. Leskin wants to ask some questions
2 about animal studies, I'm sure she can show him.
3 But he doesn't talk about animal studies. He didn't
4 list animal studies as a basis of his opinion,
5 because no such animal model exists to even look at
6 this issue. And then she wants to ask about animal
7 studies because it shows up on her outline. So if
8 she's got them, she can show them to him.

9 MR. HOPPER: And I just want to add to that,
10 same objection, but it's -- we're offering him as a
11 case-specific expert and to qualify him as a
12 case-specific expert and not as a generic expert,
13 which might more validate a line of questioning in
14 that regard. He can certainly answer, and I don't
15 intend to impede --

16 THE WITNESS: Ms. Leskin, may I supplement my
17 answer to that?

18 MR. HOPPER: -- the -- the deposition.

19 SPECIAL MASTER BORG: Well, Ms. Leskin, do you
20 have a --

21 MS. LESKIN: Well, yeah, there's too many
22 things going on. What do you want me to respond to?

23 SPECIAL MASTER BORG: Two things. Do you have
24 a proffer in response to the objection, and then do
25 you want to let Dr. Sher amend his response?

157

1 MS. LESKIN: I do want to hear what he has --

2 MR. HOPPER: May I ask if you're ruling on the
3 objections first or --

4 SPECIAL MASTER BORG: Well, no, because I want
5 to hear what it is she has to say in response and to
6 why she thinks this is within the scope.

7 MR. HOPPER: Oh, okay.

8 MS. LESKIN: I'm allowed to test what the
9 witness has or has not considered in reaching his
10 opinion. I'm asking if he has considered the animal
11 testing. If the -- if the animal testing is
12 contrary to his opinion and he hasn't considered it,
13 that's a relevant inquiry under the law.

14 MR. HOPPER: Well, and I will also enter an
15 asked-and-answered objection, because, as Neil said,
16 there's -- excuse me -- as Neil Overholtz said,
17 there's nothing in his report that even refers to
18 animal studies.

19 You can ask the questions. I don't care,
20 Judge. I just think it's important to get it on the
21 record that he's qualified as a case-specific
22 expert, and it goes beyond the scope of his report.

23 SPECIAL MASTER BORG: Okay. It's clearly on
24 the record. It's --

25 MR. OVERHOLTZ: But I just think if she's going

40 (Pages 154 to 157)

VERITEXT REPORTING COMPANY

www.veritext.com

(212) 279-9424

(212) 490-3430

| | |
|--|---|
| <p style="text-align: right;">158</p> <p>1 to ask specifics about studies, she needs to show</p> <p>2 the witness. He's not --</p> <p>3 MS. LESKIN: Well, I asked --</p> <p>4 SPECIAL MASTER BORG: Well, we will deal with</p> <p>5 those from a foundation and otherwise standpoint --</p> <p>6 MR. HOPPER: Sure.</p> <p>7 SPECIAL MASTER BORG: -- when and if the time</p> <p>8 that occurs. So it's overruled for purposes of the</p> <p>9 scope.</p> <p>10 And what would you like to do with Dr. Sher</p> <p>11 here? He had something to add.</p> <p>12 MS. LESKIN: Let me hear what he has to add.</p> <p>13 MR. HOPPER: And then you will decide whether</p> <p>14 or not you want to hear it?</p> <p>15 MS. LESKIN: Well, no. I'm happy to hear what</p> <p>16 he wants to say, because I --</p> <p>17 THE WITNESS: I guess I --</p> <p>18 MS. LESKIN: -- if it goes to whether he</p> <p>19 considered animal studies are not.</p> <p>20 THE WITNESS: Well, I'm sorry. I'm just</p> <p>21 answering your previous question, because you asked</p> <p>22 me that if I could come up with where I remembered</p> <p>23 reading it, and I remembered where I read it --</p> <p>24 MS. LESKIN: Perfect.</p> <p>25 THE WITNESS: -- the adverse event.</p> | <p style="text-align: right;">160</p> <p>1 some kind of entity.</p> <p>2 Q. And have you reviewed the analysis performed by</p> <p>3 Public Citizen in that document?</p> <p>4 A. No. I -- I, first of all, don't -- don't know</p> <p>5 Public Citizen, and I don't -- no one's asked me to</p> <p>6 review it. But I have no reason to think that Public</p> <p>7 Citizen lied.</p> <p>8 Q. Do you know, do you have an opinion as to</p> <p>9 whether it's appropriate to do the type of adverse</p> <p>10 event analysis that Public Citizen did?</p> <p>11 A. I really --</p> <p>12 MR. HOPPER: Objection; irrelevant.</p> <p>13 THE WITNESS: I can't -- I can't answer that.</p> <p>14 Because I don't know what kind of analysis they did.</p> <p>15 I'm just repeating from Dr. Blume.</p> <p>16 SPECIAL MASTER BORG: It's overruled.</p> <p>17 THE WITNESS: I'm sorry.</p> <p>18 SPECIAL MASTER BORG: All right. No, that's</p> <p>19 okay. You're fine.</p> <p>20 BY MS. LESKIN:</p> <p>21 Q. Okay. Going back to the discussion of animal</p> <p>22 studies, it's a simple -- it's actually relatively</p> <p>23 simple. Did you consider animal studies that had been</p> <p>24 done by Pfizer in reaching your opinion in this case?</p> <p>25 A. Specifically which study? When drugs are</p> |
| <p style="text-align: right;">159</p> <p>1 BY MS. LESKIN:</p> <p>2 Q. Okay.</p> <p>3 A. And it was in Dr. Blume's report. And -- and</p> <p>4 I'll -- and I'll read it so there's no mistake. "In</p> <p>5 the FDA adverse event reporting system database,</p> <p>6 during" --</p> <p>7 MR. HOPPER: Page, Doctor?</p> <p>8 THE WITNESS: I'm sorry. Page 12 of her</p> <p>9 report. "During the period between January 1, '98</p> <p>10 and December 31st, '04, Viagra was associated with</p> <p>11 the highest number of ION reports, 19 percent in the</p> <p>12 adverse event reporting system database across all</p> <p>13 reported drug products."</p> <p>14 And I took that to mean every drug that anybody</p> <p>15 ever had an adverse event in the universe of drugs</p> <p>16 that were reported to the FDA, 1 in 5 had to do with</p> <p>17 Viagra.</p> <p>18 And -- and I'm sorry, I just couldn't remember</p> <p>19 that before. But it was in Dr. Blume's report of</p> <p>20 12-1-08.</p> <p>21 BY MS. LESKIN:</p> <p>22 Q. And Dr. Blume is referring to a petition filed</p> <p>23 by Public Citizen; correct?</p> <p>24 A. I believe that's where they got the adverse</p> <p>25 events. I guess it's hard to get them unless you're</p> | <p style="text-align: right;">161</p> <p>1 performed and -- drugs are -- are developed, there are</p> <p>2 all sorts of dosing and toxicity tests and animal tests</p> <p>3 and fetus tests and things. And -- and I'm sure that</p> <p>4 it probably would fill rooms like this with those</p> <p>5 documents. I -- I don't have access to them, and I</p> <p>6 haven't looked. But if it's a specific thing, I'd be</p> <p>7 happy to review it.</p> <p>8 Q. Sure.</p> <p>9 (Sher Exhibit No. 9, 27-page document entitled</p> <p>10 Appendix XII Sildenafil - Visual Summary, was marked</p> <p>11 for identification.)</p> <p>12 BY MS. LESKIN:</p> <p>13 Q. Let me hand you what we have marked as</p> <p>14 Exhibit 9. And Exhibit 9 is Appendix XII to the NDA in</p> <p>15 this case. Have you seen this document before?</p> <p>16 A. No.</p> <p>17 Q. And did you consider this document in reaching</p> <p>18 your opinion?</p> <p>19 A. How could I have considered it if I haven't</p> <p>20 seen it?</p> <p>21 Q. Okay. So the answer to this question is no;</p> <p>22 right?</p> <p>23 A. That's correct.</p> <p>24 MR. HOPPER: Your -- Your Honor, I guess I</p> <p>25 would ask for an instruction in that the witness has</p> |

41 (Pages 158 to 161)

| | |
|--|---|
| <p style="text-align: right;">162</p> <p>1 testified that he hasn't seen it, he hasn't relied 2 upon it. If Ms. Leskin intends to ask him 3 questions, I guess my first -- 4 SPECIAL MASTER BORG: Why don't we wait and see 5 whether or not she does. 6 MS. LESKIN: All right. 7 MR. HOPPER: All right. Fair enough. 8 Absolutely. 9 (Sher Exhibit No. 10, 25-page document entitled 10 Viagra (sildenafil citrate) Tablets, was marked for 11 identification.) 12 MS. LESKIN: I'm past it. I'm handing you what 13 we have marked as Exhibit 10. 14 MR. HOPPER: You're done? 15 MS. LESKIN: Yes. Oh, wait. Hold on. 16 MR. HOPPER: So -- so you're finished with -- 17 with that? 18 MS. LESKIN: I'm finished with Exhibit 9. 19 MR. HOPPER: Okay. 20 MS. LESKIN: Marked as Exhibit 10 is the 21 labeling for Viagra. 22 THE WITNESS: Which labeling? What year? 23 BY MS. LESKIN: 24 Q. Well, if you look at the last page, it's as of 25 August 2008.</p> | <p style="text-align: right;">164</p> <p>1 A. I do. 2 Q. And you're aware that this statement and this 3 paragraph was added to the label in July 2005; correct? 4 A. I -- I knew it was in '05. I couldn't remember 5 the exact date, yes. 6 MS. LESKIN: We're on Page 23. 7 MR. HOPPER: Yeah. Thank you. 8 BY MS. LESKIN: 9 Q. And that first sentence, that's a true 10 statement; correct? 11 A. Yes. 12 Q. Okay. The next sentence says, "Most, but not 13 all, of these patients have underlying anatomic or 14 vascular risk factors for developing NAION, including, 15 but not necessarily limited to: Low cup-to-disc 16 ratio," what we've called a crowded disc -- 17 A. Right. 18 Q. -- "age over 50, diabetes, hypertension, 19 coronary artery disease, hyperlipidemia, and smoking." 20 That's a true statement; correct? 21 MR. OVERHOLTZ: Object to form; lack of 22 foundation. Still has not established that he has 23 knowledge of these people. 24 SPECIAL MASTER BORG: It's overruled. 25 Do you understand -- Are you able to answer the</p> |
| <p style="text-align: right;">163</p> <p>1 A. Thank you. 2 Q. Okay. Have you seen this label before? 3 A. I have. 4 Q. Okay. I will ask you to turn to Page 23 of the 5 document for me, please. You will see there's a 6 section entitled "Special Senses" on the bottom. 7 There's actually two on there. 8 A. Yes. 9 Q. Okay. And this is -- was within the section of 10 Post-Marketing Experience of the label; correct? If 11 you look at the prior page, you'll see that. 12 MR. OVERHOLTZ: It is. 13 THE WITNESS: Yes. 14 MR. HOPPER: Without a doubt. 15 BY MS. LESKIN: 16 Q. And you see there's a paragraph there that 17 starts, "Non-arteritic anterior ischemic optic 18 neuropathy." 19 A. Yes. 20 Q. And it says, "NAION, a cause of decreased 21 vision, including permanent loss of vision, has been 22 reported rarely post-marketing in temporal association 23 with the use of phosphodiesterase type 5 (PDE-5) 24 inhibitors, including Viagra." Do you see that 25 statement?</p> | <p style="text-align: right;">165</p> <p>1 question, Doctor? 2 THE WITNESS: Well, I don't know what these 3 people and what you're asking me. Are you asking me 4 are you reading it correctly? You read it 5 correctly. 6 BY MS. LESKIN: 7 Q. Okay. 8 A. Are you asking me if these conditions lead -- 9 possibly lead to NAION? And the answer is yes. I'm -- 10 I'm not sure what the other question was. 11 Q. Well, the question was is that a true statement 12 as to whether these -- the patients in the reports have 13 had some of these -- most -- most, but not all -- 14 A. Yeah. 15 Q. -- of those patients have had these risk 16 factors? 17 A. Yeah. Yeah, I think so. 18 Q. Okay. 19 A. That, I would agree with that. 20 Q. And the last sentence in that paragraph says, 21 "It is not possible to determine whether these events 22 are related directly to the use of PDE-5 inhibitors, to 23 the patient's underlying vascular risk factors or 24 anatomical defects, to a combination of these factors, 25 or to other factors"?</p> |

42 (Pages 162 to 165)

| | |
|--|---|
| <p style="text-align: right;">166</p> <p>1 MR. OVERHOLTZ: Objection; lack of foundation.</p> <p>2 SPECIAL MASTER BORG: Overruled.</p> <p>3 MR. HOPPER: Are you --</p> <p>4 BY MS. LESKIN:</p> <p>5 Q. Did I read that sentence correctly?</p> <p>6 A. Yes, you did.</p> <p>7 Q. And do you agree with that statement?</p> <p>8 MR. OVERHOLTZ: Object; lack of foundation that</p> <p>9 he -- that he's ever analyzed these reports --</p> <p>10 SPECIAL MASTER BORG: It's overruled.</p> <p>11 MR. OVERHOLTZ: -- to make a causal</p> <p>12 determination.</p> <p>13 SPECIAL MASTER BORG: It's overruled.</p> <p>14 THE WITNESS: I don't agree with the statement,</p> <p>15 because I think it is possible in some of these</p> <p>16 events to clearly indicate that the PDE-5 inhibitor</p> <p>17 was the cause or more than likely is the cause, or</p> <p>18 probably, depending on how you want to define it.</p> <p>19 And I believe that this label is talking about</p> <p>20 every event. And -- and I'm here to be more</p> <p>21 specific about the two gentlemen we have here. So I</p> <p>22 don't agree with that, because the statement says</p> <p>23 "whether these events." And I would imagine that</p> <p>24 these events refer to all the adverse events, and</p> <p>25 I -- I don't agree with that, because I think in</p> | <p style="text-align: right;">168</p> <p>1 A. Yes, ma'am.</p> <p>2 Q. Okay. And is it fair to say that part of what</p> <p>3 you've done on these two cases is conduct a</p> <p>4 differential diagnosis?</p> <p>5 A. No. I don't -- differential di -- well,</p> <p>6 differential diagnosis is when someone comes in with a</p> <p>7 headache. You say, well, is this sinuses? Is it their</p> <p>8 spouse driving them nuts? Is it muscle tension? Is it</p> <p>9 migraine? So on and so forth. And you make a list.</p> <p>10 And then you take -- Then you speak to the patient and</p> <p>11 you analysis it and use your knowledge, and you make a</p> <p>12 diagnosis. So, if that explains it.</p> <p>13 Q. I want to talk about --</p> <p>14 A. Are we ready for a break?</p> <p>15 Q. Do you need a break? Absolutely.</p> <p>16 A. I'm out of Pepsi.</p> <p>17 MR. HOPPER: What's -- what's your time --</p> <p>18 MR. BECNEL: 12:15.</p> <p>19 MR. HOPPER: Lori, what's your -- How much time</p> <p>20 do you have left, do you think?</p> <p>21 THE VIDEOGRAPHER: We are now going off the</p> <p>22 video record. The time is 12:13 p.m.</p> <p>23 (A discussion was held off the record.)</p> <p>24 SPECIAL MASTER BORG: 35 minutes.</p> <p>25 (A short break was held from 12:16 p.m. to 1:00</p> |
| <p style="text-align: right;">167</p> <p>1 some of these events it is associated.</p> <p>2 BY MS. LESKIN:</p> <p>3 Q. Is it your view that you can only determine</p> <p>4 whether Viagra can cause NAION by looking at an</p> <p>5 individual patient?</p> <p>6 MR. OVERHOLTZ: Object to form; lack of</p> <p>7 foundation.</p> <p>8 SPECIAL MASTER BORG: Overruled.</p> <p>9 THE WITNESS: I think that you have to examine</p> <p>10 the patient, examine the circumstance, and look at</p> <p>11 the totality of facts for each case. I -- I don't</p> <p>12 want to give a blanket statement that all cases of</p> <p>13 people who take NAION -- who use these drugs have</p> <p>14 NAION. But I'm only -- I'm limiting my answers to</p> <p>15 particularly for the two cases that I was asked to</p> <p>16 give an opinion on. I just can't do it about all</p> <p>17 these cases.</p> <p>18 MR. HOPPER: And, Your Honor, I would insert on</p> <p>19 the record, again, he is a case-specific expert.</p> <p>20 He's not here to testify as a generic expert across</p> <p>21 a population.</p> <p>22 SPECIAL MASTER BORG: Go ahead, Ms. Leskin.</p> <p>23 BY MS. LESKIN:</p> <p>24 Q. Doctor, are you familiar with the term</p> <p>25 "differential diagnosis"?</p> | <p style="text-align: right;">169</p> <p>1 p.m.)</p> <p>2 THE VIDEOGRAPHER: We are now back on the video</p> <p>3 record. The time is 1:00 p.m.</p> <p>4 (Sher Exhibit No. 11, one-page document, an</p> <p>5 e-mail from Neal A. Sher, M.D., to rrh@zimmreed.com,</p> <p>6 Subject: Retainer agreement, was marked for</p> <p>7 identification.)</p> <p>8 BY MS. LESKIN:</p> <p>9 Q. Dr. Sher, I'm handing you what we've marked as</p> <p>10 Exhibit 11. And even though my name appears on the</p> <p>11 top, this is an e-mail from the disk that you provided</p> <p>12 to me today.</p> <p>13 A. Yes.</p> <p>14 Q. Can you confirm that that is, in fact, a copy</p> <p>15 of the e-mail from your disk?</p> <p>16 A. Yeah.</p> <p>17 Q. Okay. And apparently when I opened it up on my</p> <p>18 computer, it opened up in my Microsoft Outlook and</p> <p>19 ended up with my name on it.</p> <p>20 A. Oh.</p> <p>21 Q. But I wasn't involved in this original e-mail</p> <p>22 correspondence; correct?</p> <p>23 A. Okay.</p> <p>24 Q. Right?</p> <p>25 A. Yes.</p> |

43 (Pages 166 to 169)

170

1 Q. You didn't write me any e-mails in 2008?
 2 A. I've never -- I've never met you before or
 3 written to you.
 4 Q. Okay. Now this is an e-mail that you wrote to
 5 Mr. Hopper; correct?
 6 A. Yes.
 7 Q. That's the rrh@zimmreed e-mail address? You
 8 recognize that, that that's Mr. Hopper's?
 9 A. It is.
 10 Q. Okay. And if you look at the e-mail, it says
 11 that you've received the retainer from Mr. Becnel on
 12 December 12th, 2006, and that's what we talked about
 13 earlier today; correct?
 14 A. Right.
 15 Q. And then the next sentence says, "That retainer
 16 has been most -- almost used up, and I have not done
 17 any work on this case since February 21st, 2007." Do
 18 you see that?
 19 A. That's correct, yeah.
 20 Q. Now the original e-mail that we looked at
 21 between you and Mr. Becnel was from May of 2005. Do
 22 you recall that?
 23 A. The one I gave you the hard copy of, yes.
 24 Q. Yes. What work had you done between May of
 25 2005 and February 21st of 2007?

171

1 A. Almost all the work that was done was in May of
 2 2005, and there was nothing else really afterwards.
 3 They didn't ask me anything until I heard from Mr.
 4 Hopper when I started doing the case again. There
 5 really wasn't anything.
 6 Q. Well, to say there really wasn't anything --
 7 A. Well, I mean --
 8 Q. Yet your e-mail refers to a date of
 9 February 21st, 2007. So was there something between
 10 May of 2005 when you wrote the e-mail and
 11 February 21st, 2007, which --
 12 A. Oh. Uh-huh.
 13 Q. -- is the date that you put in the e-mail --
 14 this e-mail?
 15 A. I -- I -- Yeah, I don't recall. Sometimes Mr.
 16 Becnel may have sent me a document. I don't think I
 17 billed him for -- for anything. I just -- I don't
 18 recall. I probably looked at the Becnel log. And
 19 sometimes I get copies of articles and things like he
 20 might send me the revised FDA label or something like
 21 that to -- to look at. I don't think I charged for
 22 that. Sometimes I just get articles in the mail and if
 23 I -- I put them in a folder. I don't necessarily read
 24 them at the time.
 25 Q. Well, you wrote here that the retainer has been

172

1 almost used up so --
 2 A. Right. I spent about six -- five, six hours
 3 initially, so it -- it -- it used it up.
 4 Q. Okay. So your testimony is that the original
 5 \$2,500 was used up back in May of 2005?
 6 A. Right.
 7 Q. When you originally wrote your e-mail?
 8 A. That's correct. And I don't think I billed Mr.
 9 Becnel anything else. And then Mr. Hopper engaged me
 10 in August, and I really haven't -- I'm pretty much --
 11 all the subsequent work has been with the Zimmerman
 12 Reed firm, if that clarifies it.
 13 Q. And between May of 2005 and December of 2006,
 14 you weren't paid for that original time?
 15 A. I don't think I did anything else other than
 16 this initial report. But I'd -- I'd have to check
 17 back.
 18 Q. Okay. But you weren't paid for that original
 19 report until December 12th, 2006?
 20 A. I'm a little confused.
 21 MR. HOPPER: I'm confused, too. I apologize.
 22 BY MS. LESKIN:
 23 Q. Okay. That's fine. The second sentence of the
 24 e-mail --
 25 MR. HOPPER: It may be the use of your terms

173

1 "original" and stuff like that that might be
 2 throwing us both off.
 3 BY MS. LESKIN:
 4 Q. The second sentence of your e-mail, right, that
 5 we have marked as Exhibit 11 says, "Please note that I
 6 have received a retainer" --
 7 A. Oh, I -- Yeah.
 8 Q. Let me just ask the question.
 9 A. I'm sorry.
 10 Q. "I received a retainer of \$2,500 from the
 11 Becnel Law Firm on December 12th, 2006."
 12 Your original e-mail that we marked first thing
 13 this morning was dated May of 2005; correct?
 14 A. Yes.
 15 Q. So am I correct that you were not paid for the
 16 report that you prepared in May of 2005 --
 17 A. No.
 18 Q. -- until November of 2006?
 19 A. No. I think it's incorrect. I think I billed
 20 for that report. And then unsolicited, I received a --
 21 I don't recall. I'd have to check back the billing
 22 records, and I can get them to you between me and the
 23 Becnel firm. I just forgot about doing that. Mostly I
 24 have been dealing with Mr. Hopper.
 25 But I received a retainer -- In fact, it was a

44 (Pages 170 to 173)

| | |
|--|---|
| <p style="text-align: right;">174</p> <p>1 little odd, because I didn't bill Mr. Becnel, and he 2 sent me a check. I wish all my people would do that. 3 And I don't recall the hours where I still may 4 owe Mr. Becnel money. It's a little confusing to me 5 when I'm dealing with two firms of who's engaging me 6 and that. I know you lawyers have it all worked out, 7 but I don't. 8 Q. Well, not really, but ... 9 A. So I'd have to check back my invoices, and I 10 could provide that if you -- if you feel it's 11 necessary. 12 (Sher Exhibit No. 12, two-page document 13 entitled Neal A. Sher MD FACS Consulting Work Log, 14 was marked for identification.) 15 BY MS. LESKIN: 16 Q. I'm going to hand you what we've just marked as 17 Exhibit 12. 18 A. Right. 19 Q. And this is -- Exhibit 12 is the invoice that 20 we were looking at on my computer -- 21 A. Yeah. 22 Q. -- earlier today. 23 A. Sure. 24 Q. I have now been able to figure out the computer 25 system here and print out a copy.</p> | <p style="text-align: right;">176</p> <p>1 MS. LESKIN: I'm not saying there's anything 2 hidden. I'm just asking for a copy. 3 MR. HOPPER: He got retained. He had certain 4 administrative matters and certain things he did 5 relative to the retainer. He wasn't asked to do any 6 more work. 7 MS. LESKIN: Okay. 8 MR. HOPPER: And then he was asked to do work 9 again. It's that simple. 10 MS. LESKIN: I'm not asking for -- 11 MR. HOPPER: You're entitled. 12 MS. LESKIN: -- your testimony. I'm not asking 13 for your clarification. 14 MR. HOPPER: I understand, but you're entitled 15 to get it. I'm just giving you clarification and 16 clarifying it for the record, but I -- 17 MS. LESKIN: I understood his testimony 18 perfectly. 19 MR. HOPPER: It's that simple. 20 THE WITNESS: I'll be -- I'll be happy to 21 provide it. 22 MS. LESKIN: Thank you, Doctor. 23 MR. OVERHOLTZ: Overruled. That's off the 24 record. 25 THE WITNESS: Thank you, Judge.</p> |
| <p style="text-align: right;">175</p> <p>1 A. Okay. 2 Q. Does this look like the -- Well, first, confirm 3 for me, is this, in fact, the spreadsheet that we were 4 looking at earlier today? 5 A. It is. 6 Q. And this is the spreadsheet that you provided 7 to me this morning on that disk; correct? 8 A. Right. 9 Q. Now -- So am I understanding correctly that 10 this spreadsheet that we've marked as Exhibit 12 are 11 your billing records solely with the Zimmerman Reed 12 firm? 13 A. That's correct. 14 Q. Okay. And you may have on your computer 15 somewhere separate billing records reflecting time 16 spent with Mr. Becnel's firm? 17 A. Right. And I had -- When I was preparing this 18 the other night, not -- not either found them usually 19 or not included them. But I do have some, yeah. 20 Q. We would ask for copies of any spreadsheets for 21 time spent with the Becnel law firm. 22 MR. HOPPER: There's -- there's -- it's -- it's 23 a difference without a distinction, to be quite 24 honest with you. But happy to provide you. There's 25 no hidden agendas or anything here.</p> | <p style="text-align: right;">177</p> <p>1 (A discussion was held off the record.) 2 BY MS. LESKIN: 3 Q. I'd like to turn now to your expert reports 4 for Mr. -- Well, let's start with Mr. Stanley. And I 5 think we started -- We marked your expert report as 6 Exhibit 1 earlier today; is that right? 7 A. Yes, that's right. 8 Q. Okay. Do you have Mr. Stanley's report in 9 front of you? 10 A. I do. I also have his chart here, as well. 11 Q. Okay. Now when Mr. Stanley came into your 12 office for examination, did he fill out a new patient 13 form? 14 A. He filled out some cards. But I did have very 15 complete records, so I didn't -- Usually, in these 16 cases, refer to the records that were sent to me, which 17 were pretty extensive. And -- But he did, and I have 18 it here. 19 Q. Okay. Now if you look at the bottom of Page 2 20 of your report for Mr. Stanley, you write it's your -- 21 your opinion that the visual loss this patient has 22 sustained is a result of Mr. Stanley's use of 23 sildenafil; is that correct? 24 A. Yes. 25 Q. And you base that opinion, according to your</p> |

45 (Pages 174 to 177)

178

1 report, on the history, temporal relationship of
2 sildenafil use, and the clinical findings of Mr.
3 Stanley's case; right?
4 A. Yes.
5 Q. Okay. I want to go through each of those.
6 What clinical findings did you -- in Mr. Stanley's case
7 led you to conclude that sildenafil caused his NAION?
8 A. Mr. Stanley is a 76-year-old gentleman at the
9 time I saw him. And he noticed -- He had had a prior
10 retinal detachment. He came in. And when I -- when I
11 exam -- I'm sorry. When I examined him, he was -- had
12 a vision of 20/30 in the right eye and -- and was
13 legally blind in his left eye.
14 I'm just giving you some of the positive
15 findings to save time. He had evidence of a repaired
16 retinal detachment. He had a visual field that was
17 severely impaired and blacked out. He had what we call
18 sort of an aspirin tablet optic nerve. It was very
19 pale and white and -- and was ischemic.
20 Q. Any other clinical findings lead you to
21 conclude that sildenafil caused his NAION?
22 A. You asked me for the clinical findings on my
23 eye exam, not for my conclusions, that I can
24 understand. I mean --
25 Q. Well, let me go back. I believe my question

179

1 was you wrote in your report, "The visual loss this
2 patient has sustained is the result of Mr. Stanley's
3 use of sildenafil. This opinion is based on the
4 history, temporal relationship of sildenafil use, and
5 the clinical findings of Mr. Stanley's case."
6 A. That's right.
7 Q. So what I asked was what clinical findings of
8 Mr. Stanley's case supports your opinion that his NAION
9 was caused by sildenafil?
10 A. In the review of all the records for Mr.
11 Stanley, and the review of my findings and the -- and
12 the temporal relations, the history of the drug he
13 took, the symptoms that he experienced, the -- and
14 review of his other records, which, when one sees the
15 patient, one examines that, it's medically probable to
16 -- medically probable that Mr. Stanley's -- would never
17 have had ischemic optic neuropathy as he presented
18 unless -- if he hadn't taken the ED drug.
19 Q. In your practice, your normal clinical
20 practice, when you discuss clinical findings, does that
21 refer solely to your examination of the patient, or
22 does that refer to your review of records and other
23 things?
24 A. I think clinical findings is limited to the
25 portions of the examination that are related to what I

180

1 see and probably the -- some of the laboratory results,
2 if it's -- if it's rel -- if it's relevant.
3 Q. Okay. So the clinical findings for Mr.
4 Stanley's case would be what you saw and the lab
5 results; correct?
6 A. That's correct.
7 Q. Okay. So what clinical findings for Mr.
8 Stanley's case support a finding that his NAION was
9 caused by sildenafil?
10 A. The clinical findings were that he was -- had
11 optic atrophy and had experienced an event in the left
12 eye that was consistent with NAION. And the clinical
13 findings went along with that 100 percent.
14 Q. Okay. So the clinical findings, is it fair to
15 say, support the diagnosis of NAION?
16 A. They did.
17 Q. Okay. Is there anything from the clinical
18 findings that allows you to conclude that the NAION was
19 caused by sildenafil?
20 A. Not alone, no.
21 Q. The other thing you identify is the history.
22 And you've told me just now that you reviewed all of
23 his records and the history of the drug he took and the
24 symptoms. What from -- What aspects of Mr. Stanley's
25 history supports your opinion that Viagra caused his

181

1 vision loss?
2 A. The patient was on the drug. He had been using
3 it since the year 2000. He would usually -- usually
4 use it weekly. And the drug was used in the day
5 preceding the visual loss. He didn't notice the visual
6 loss until the next morning. And, presumably, it
7 occurred during the night.
8 Q. Anything else about his history?
9 A. Well, there's a lot of other things about his
10 history in terms of that he had a history of
11 hypertension, and he was on a number of medicines. He
12 was of somewhat advanced age. Also, in terms of my
13 general impression, he was -- was a very reliable,
14 observant, intelligent gentleman, a retired banker,
15 worked at the bank across the street from me -- or the
16 corporation, and was -- was very precise and -- and
17 accurate in -- in his descriptions of some of his
18 symptoms and his issues. I had no reason to think he
19 was not truthful with me.
20 I have -- based on clinical experience, can
21 tell when patients are malingering or not. And he
22 appeared to be very straightforward.
23 Q. You said that you -- one of the aspects of his
24 history that you found significant is that he had been
25 on Viagra; correct? Using it since 2000?

46 (Pages 178 to 181)

VERITEXT REPORTING COMPANY

(212) 279-9424

www.veritext.com

(212) 490-3430

| | |
|--|---|
| <p style="text-align: right;">182</p> <p>1 A. That's right.</p> <p>2 Q. Was what the basis for that?</p> <p>3 A. That was from his records. I believe that he</p> <p>4 was given 50-milligram samples of Viagra by his, I</p> <p>5 think, urologist, after his prostate cancer surgery in</p> <p>6 March of 2000.</p> <p>7 THE VIDEOGRAPHER: Excuse me, Doctor. You're</p> <p>8 blocking your microphone with your hand.</p> <p>9 THE WITNESS: Oh, I'm sorry. I'm sorry.</p> <p>10 THE VIDEOGRAPHER: Thank you.</p> <p>11 BY MS. LESKIN:</p> <p>12 Q. You said that you understood that Mr. Stanley</p> <p>13 usually used Viagra weekly. Did I understand that</p> <p>14 correctly?</p> <p>15 A. That's what he told me.</p> <p>16 Q. Okay. He told you that?</p> <p>17 A. He told me.</p> <p>18 Q. Did he tell you whether there was a particular</p> <p>19 day during the week that he normally used Viagra?</p> <p>20 MR. HOPPER: Objection; irrelevant.</p> <p>21 SPECIAL MASTER BORG: Overruled.</p> <p>22 THE WITNESS: No. He said the word "weekly,"</p> <p>23 and that's what I wrote down.</p> <p>24 BY MS. LESKIN:</p> <p>25 Q. Okay.</p> | <p style="text-align: right;">184</p> <p>1 A. I'm -- I'm sorry. I don't understand your</p> <p>2 questions.</p> <p>3 Q. After he had suffered his NAION event, and --</p> <p>4 A. Well, that would be a visual side effect.</p> <p>5 Q. Okay. Assume --</p> <p>6 A. Yeah.</p> <p>7 Q. Other than NAION, what -- After the onset of</p> <p>8 his NAION, you testified that you understood Mr.</p> <p>9 Stanley continued to take Viagra for a year; correct?</p> <p>10 A. That's correct.</p> <p>11 Q. During that year, did he have any additional</p> <p>12 visual side effects from Viagra?</p> <p>13 A. And I'm not aware of any.</p> <p>14 Q. Okay. Now you note in your report that you</p> <p>15 reviewed records from Dr. Pelletier?</p> <p>16 A. Yes.</p> <p>17 Q. Do you know Dr. Pelletier?</p> <p>18 A. I do.</p> <p>19 Q. Okay. And did you discuss Mr. Stanley's</p> <p>20 history with Dr. Pelletier?</p> <p>21 A. I did not.</p> <p>22 Q. Now in 1987, Dr. Pelletier's records indicate</p> <p>23 that Mr. Stanley had a retinal pigment epithelial</p> <p>24 atrophy; correct?</p> <p>25 A. Yes.</p> |
| <p style="text-align: right;">183</p> <p>1 A. If he may have said the day, I don't remember</p> <p>2 it.</p> <p>3 Q. Do you know how many times Mr. Stanley had</p> <p>4 taken Viagra prior to the onset of his NAION?</p> <p>5 A. I do not.</p> <p>6 Q. Do you know how many times Mr. Stanley took</p> <p>7 Viagra after the diagnosis of his NAION?</p> <p>8 A. Yes. I believe that he continued to take it</p> <p>9 for approximately one year following the episode of</p> <p>10 visual loss. I'm not sure how many times, but ...</p> <p>11 whether that was weekly, or his blindness slowed down</p> <p>12 his sexual activity or which -- I -- I don't know</p> <p>13 whether his loss of vision --</p> <p>14 Q. So you don't know how often he took it</p> <p>15 following the onset of NAION?</p> <p>16 A. I -- I do not. He did say that he continued to</p> <p>17 take it after this because no one told him to stop.</p> <p>18 And he indicated -- and I gleaned from the records, and</p> <p>19 I don't recall which record -- that he took it for</p> <p>20 about a year.</p> <p>21 Q. Prior to the onset of his NAION, did Mr.</p> <p>22 Stanley have any other visual side effects from Viagra?</p> <p>23 A. No.</p> <p>24 Q. Subsequent to the onset of NAION, did Mr.</p> <p>25 Stanley have any visual side effects from Viagra?</p> | <p style="text-align: right;">185</p> <p>1 Q. And Dr. Pelletier was unable to rule out</p> <p>2 papillitis at the time; correct?</p> <p>3 A. No. I -- I have the document and the note.</p> <p>4 I'm just looking at ophthalmologic shorthand. Retinal</p> <p>5 pigment epithelial atrophy is very common. It usually</p> <p>6 means it's some aging in portions of the retina.</p> <p>7 Dr. Pelletier did an examination. The</p> <p>8 patient's vision at the time was 20/20 in each eye.</p> <p>9 And in looking at his note, I don't feel that he was</p> <p>10 concerned about any of those particular conditions.</p> <p>11 Q. I'm going to mark what's Exhibit 13. I know</p> <p>12 you have a copy of Dr. Pelletier's records, but for the</p> <p>13 deposition purpose --</p> <p>14 A. Sure.</p> <p>15 Q. -- I'm going to mark a set of records we</p> <p>16 received from the St. Paul Eye Clinic which include Dr.</p> <p>17 Pelletier's records in this case.</p> <p>18 (Sher Exhibit No. 13, 33-page document entitled</p> <p>19 Certification of Records for Richard Stanley from</p> <p>20 the St. Paul Eye Clinic, was marked for</p> <p>21 identification.)</p> <p>22 BY MS. LESKIN:</p> <p>23 Q. And if you look at the -- See the bottom</p> <p>24 right-hand corner, there's a series of Bates numbers?</p> <p>25 A. Yes.</p> |

47 (Pages 182 to 185)

| | |
|---|---|
| <p style="text-align: right;">186</p> <p>1 Q. Those are numbers that we put on in order to 2 help track the -- the pages of the exhibit. 3 A. Sure. 4 Q. If you look at the one that's marked 10 -- 5 A. Yes. I've seen that one. 6 Q. Do you see that? 7 A. Yes. 8 Q. And that's a visit dated February 12th, 1987 -- 9 the top part of that? 10 A. Right. 11 Q. And that indicates -- the dictation lines 12 indicate that Dr. Pelletier was the doctor; correct? 13 A. That's correct. 14 Q. And the last line of that entry reads, "At this 15 stage, I cannot say for sure that there wasn't some 16 papillitis, but it's not visible at this time." That 17 was Dr. Pelletier's conclusions in 1987; correct? 18 A. That's correct. 19 Q. Now what is papillitis? 20 A. Papillitis is an inflammation of the optic 21 nerve most commonly from certain diseases, Ms. Leskin, 22 like multiple sclerosis. And there is profound loss of 23 vision in papillitis. And that's why my review of 24 this, when I looked at Dr. Pelletier, who is a retinal 25 specialist -- I think he's long since retired but --</p> | <p style="text-align: right;">188</p> <p>1 memorize every word. 2 Q. Did you review Mr. Stanley's deposition before 3 this past week? 4 A. No. 5 Q. That was the first time you read his 6 deposition? 7 A. It was the first time I was sent it, yes. 8 Q. You read -- Do you recall that Mr. Stanley 9 testified that there was gradual improvement to the 10 right eye following this incident in 1987? 11 A. I didn't put much stock in the incident in 12 1987. Basically, I felt that the patient didn't have 13 papillitis. I don't know what the cause of the 14 incident was. And it didn't persist. 15 MS. LESKIN: Objection non-responsive. 16 SPECIAL MASTER BORG: Sustained. 17 BY MS. LESKIN: 18 Q. Are you aware -- Do you recall -- do you recall 19 that Mr. Stanley testified at his deposition with 20 regard to the 1987 incident that there was gradual 21 improvement? 22 A. I -- I have no reason to dispute, if that's 23 what he said. Just what it means to you and what it 24 means to me may be in two different contexts. 25 Q. And do you recall reading in his deposition</p> |
| <p style="text-align: right;">187</p> <p>1 and he did a fluorescein angiogram, which is where one 2 injects dye in the vein and takes some pictures, there 3 was really no evidence of -- of inflammation. There 4 was some atrophy of the retina consistent with age. 5 And I think that most ophthalmologists would conclude 6 that anybody with 20/20 vision does not have 7 papillitis. 8 Q. You are aware that at his deposition, Mr. 9 Stanley testified there was a rapid onset of the 10 incident in 1987? 11 A. The incident seemed pretty vague to me. He 12 said he had a little bit of blurred vision, and I don't 13 think Dr. Pelletier could diagnose it. And in my 14 looking at all those records, my conclusions were there 15 was no optic nerve problem. And why he had some 16 blurred vision at that time was -- was not clear. But 17 it didn't persist, and it wasn't a problem. 18 MS. LESKIN: Objection; non-responsive. 19 SPECIAL MASTER BORG: Sustained. 20 BY MS. LESKIN: 21 Q. Are you aware that Mr. Stanley testified in 22 this case that at the time of the incident in 1987, 23 there was a rapid onset? 24 A. I don't recall his exact words. I -- I read 25 through his deposition in the last week, but I didn't</p> | <p style="text-align: right;">189</p> <p>1 that Mr. Stanley testified that his right eye still had 2 a little bit of sort of fuzziness since the 1987 3 incident? Do you recall reading that testimony? 4 A. Yes. 5 Q. Do you recall in reviewing Mr. Stanley's 6 medical records that in 1994, his ophthalmologist noted 7 that the right eye showed slight optic atrophy? 8 A. I feel that -- The answer is no. When you say 9 fuzziness -- And the reasons I didn't take much stock 10 is Mr. Stanley had a perfectly normal visual field when 11 I performed it on September 4th in my office. And if 12 he did have fuzziness or a blind spot or an issue, it 13 would have showed up. 14 So when I look at my findings based on my exam 15 with Mr. Martin -- Mr. Stanley -- excuse me -- and I 16 look at the previous episode, because lots of patients 17 have histories like that, my eye was fuzzy, the vision 18 was down. So, basically, the answer is I don't think 19 anything significantly went on before, because he 20 didn't have it now. 21 Lots of people have things -- reasons for 22 vision to be a little fuzzy. Their glasses could be 23 dirty or they could have some other reason. 24 MS. LESKIN: Objection to everything after the 25 word "no" as non-responsive.</p> |

48 (Pages 186 to 189)

| | |
|--|---|
| <p style="text-align: right;">190</p> <p>1 SPECIAL MASTER BORG: Sustained.</p> <p>2 BY MS. LESKIN:</p> <p>3 Q. And you did do a visual field testing when you</p> <p>4 saw Mr. Stanley; correct?</p> <p>5 A. I did.</p> <p>6 Q. And you found that the visual fields were</p> <p>7 reliable with somewhat diminished field on the right</p> <p>8 eye, but were grossly normal; correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And you will agree with me that whatever the</p> <p>11 event was in 1987, it wasn't caused by Mr. Stanley's</p> <p>12 ingestion of Viagra; correct?</p> <p>13 A. Is that a re -- is that a serious question?</p> <p>14 Q. Yes, Doctor.</p> <p>15 A. So you're saying there was Viagra in 1987?</p> <p>16 Q. No. I'm asking if you will agree with me that</p> <p>17 whatever it was that he had in 1987 --</p> <p>18 A. Oh, I'm sorry. I'm sorry. I misunderstood.</p> <p>19 Q. -- it was not caused by Viagra?</p> <p>20 A. Yeah, I agree with you.</p> <p>21 Q. All right. You told me that Mr. Stanley was</p> <p>22 hypertensive; correct?</p> <p>23 A. Yes.</p> <p>24 Q. He had a history of taking var -- several</p> <p>25 different hypertensive medications?</p> | <p style="text-align: right;">192</p> <p>1 that, because that's the wrong plaintiff.</p> <p>2 A. I'm thinking Mr. Martin.</p> <p>3 MS. LESKIN: Yeah.</p> <p>4 MR. HOPPER: How many prior questions were --</p> <p>5 BY MS. LESKIN:</p> <p>6 Q. No, the other ones are correct.</p> <p>7 A. I agree --</p> <p>8 Q. I could have stated a whole list here.</p> <p>9 A. I agree. They really should have renamed the</p> <p>10 plaintiffs without the first -- first name Richard,</p> <p>11 because --</p> <p>12 Q. I apologize for that. And thank you to Ms.</p> <p>13 Fyman for correcting me.</p> <p>14 A. Yeah.</p> <p>15 Q. You will agree with me that Mr. Stanley does</p> <p>16 not have a personal history of myocardial infarction;</p> <p>17 correct?</p> <p>18 A. There was no known myocardial infarction that I</p> <p>19 could find in the records, yes.</p> <p>20 Q. Okay. If a man came into your office with</p> <p>21 NAION with hypertension at age 69 with a history of,</p> <p>22 like I said, hypertension and atrial flutter, with a</p> <p>23 diagnosis of NAION and no other medications, the</p> <p>24 diagnosis of NAION would not be unusual in your</p> <p>25 opinion; is that right?</p> |
| <p style="text-align: right;">191</p> <p>1 A. Yes.</p> <p>2 Q. Did Mr. Stanley's hypertension put him at risk</p> <p>3 for NAION?</p> <p>4 A. Yes. I think it increased his risk.</p> <p>5 Q. Did Mr. -- What was Mr. Stanley's age at the</p> <p>6 time of his NAION event?</p> <p>7 A. I'll have to check. I'm sorry.</p> <p>8 Q. That's okay.</p> <p>9 A. Mr. Stanley was about 68 or 69.</p> <p>10 Q. And did that age put Mr. Stanley at risk for</p> <p>11 NAION?</p> <p>12 A. Yes.</p> <p>13 Q. Are you aware that Mr. Stanley also had atrial</p> <p>14 flutter?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Did atrial flutter put him at risk for</p> <p>17 NAION?</p> <p>18 A. I think atrial flutter indicates there may be</p> <p>19 some heart disease of a more general nature. And the</p> <p>20 answer would be yes.</p> <p>21 Q. And you're aware that Mr. Stanley had a TIA in</p> <p>22 the past?</p> <p>23 A. Yes.</p> <p>24 Q. And when they -- he had the TIA, they found --</p> <p>25 Oh, sorry. You know what? I'm confusing you. Strike</p> | <p style="text-align: right;">193</p> <p>1 MR. HOPPER: Objection; vague and calls for a</p> <p>2 hypothetical.</p> <p>3 SPECIAL MASTER BORG: It's overruled. If you</p> <p>4 can answer it, Doctor.</p> <p>5 THE WITNESS: "Unusual" sort of goes to</p> <p>6 incidence. And more people come into my office with</p> <p>7 glaucoma and cataract. It wouldn't be unheard of.</p> <p>8 And -- But NAION is still a rare disease. But it</p> <p>9 would not be unusual would be a fair statement.</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. Are you familiar with the term "spontaneous</p> <p>12 NAION"?</p> <p>13 A. I don't know how to define -- I'm not sure what</p> <p>14 that really means.</p> <p>15 Q. Okay. Mr. Stanley was at risk for NAION in his</p> <p>16 left eye before he ever took Viagra; isn't that a fair</p> <p>17 statement?</p> <p>18 MR. OVERHOLTZ: Object to the form; lack of</p> <p>19 foundation. The fact that he -- I mean it's -- he</p> <p>20 was at risk? He had risk factors? Those are two</p> <p>21 different questions.</p> <p>22 MS. LESKIN: You can ask your question. I'll</p> <p>23 ask mine.</p> <p>24 SPECIAL MASTER BORG: Yeah, it's overruled.</p> <p>25 Doctor, do you understand, and can you answer</p> |

49 (Pages 190 to 193)

194

1 the question?

2 THE WITNESS: He had some of the risk factors

3 for NAION, correct.

4 BY MS. LESKIN:

5 Q. If Mr. Stanley had never taken Viagra, what

6 would you say caused his NAION?

7 A. Probably a, again, series of events and

8 conditions that led to ischemia of his optic nerve,

9 possibly a loss in blood pressure -- excuse me --

10 lowering of blood pressure at night or some other

11 reasons. We just don't know. It's quite speculative.

12 THE VIDEOGRAPHER: Excuse me, Doctor. Can you

13 move your microphone back up? You just pulled it

14 down. Thank you.

15 THE WITNESS: Oh, it's -- Oh, I didn't --

16 Actually, it must have fallen. Let me -- How's

17 that?

18 THE VIDEOGRAPHER: Fine. Thank you.

19 THE WITNESS: I'm sorry. It's caught. That's

20 why. It was on my chair.

21 BY MS. LESKIN:

22 Q. How are you able to rule out that Mr. Stanley

23 would not have gotten NAION if he had never taken

24 Viagra? Well, strike that.

25 Are you able to rule out that Mr. Stanley would

195

1 never have gotten NAION if he had not taken Viagra?

2 A. I think the only way to answer that is to --

3 it -- to -- that it's medically probable and

4 scientifically probable that in this situation on the

5 date that we were talking about when he took the

6 Viagra, it led to this series of events that led to his

7 NAION.

8 I can't rule out or in the possibility that if

9 Mr. Stanley never took the drug or the drug wasn't

10 invented that he couldn't get NAION. I mean his odds

11 were 2.2 to 10.3 in 100,000 of getting it.

12 I do think to a high degree of medical

13 probability, that the fact that he did take it on that

14 particular occasion or week -- on that particular

15 occasion, that it did lead to his disease.

16 Q. And why? What's the basis for that opinion you

17 just gave me?

18 A. That's based on the totality -- and I don't

19 want to repeat myself -- from the morning, the

20 evidence, the description, and what happened to him

21 that morning. It's -- it's what happened to him on

22 that -- that series of events. I'm saying morning, but

23 I don't want to necessarily say morning -- it was in

24 his case -- and that he took this the night before. He

25 didn't use it daily. He didn't use it thousands of

196

1 times. And that in my opinion, it was medically

2 probable that taking the Viagra at that time helped

3 cause his NAION.

4 Q. If Mr. Stanley had not taken Viagra the night

5 before, but had taken it two nights before, would that

6 change your opinion?

7 A. No.

8 Q. If Mr. Stanley had taken it three nights

9 before, would that change your opinion?

10 A. The opinion is based less on the half-life of

11 the drug and more on the onset of visual symptoms that,

12 as I talked about I think at length this morning, is

13 variable and that not every visual loss is acute. And

14 that he may have taken it -- Let's just hypothetically

15 say he took it three nights before and he started to

16 have vision problems, but he was so engaged with

17 something else in his life at the time, he didn't

18 really notice it until that -- until it reached a

19 certain level. So the -- the timing of the visual loss

20 I think here is the variable and not so much the exact

21 time of the drug. Because -- So it would not change my

22 opinion.

23 Q. When did the swelling to the optic nerve in Mr.

24 Stanley's left eye begin?

25 A. It's hard to be exact. We don't know. No one

197

1 saw him exactly at that time. It was swollen when he

2 saw the first physician. I just want to -- When he saw

3 Dr. Bhavsar, it was swollen, and he sent him to Dr.

4 Weingarden.

5 Q. And you don't know how long it had been swollen

6 by the time he had seen Dr. Bhavsar; correct?

7 A. That's correct.

8 Q. Can you state to any degree of medical

9 certainty that Mr. Stanley's optic disc was not swollen

10 before he took Viagra?

11 A. At what point are we talking about?

12 Q. We're talking at the point that he started

13 having a swollen optic disc.

14 A. Unless someone was examining him, we -- no one

15 would know one way or the other.

16 Q. Let's talk about Mr. Martin. And I want to

17 turn you to Page 3 of your report on Mr. Martin. And,

18 again, you wrote -- Are you there with me?

19 A. I am.

20 Q. Okay. Under the section Discussion.

21 A. Yes.

22 Q. You wrote, "The visual loss this patient has

23 sustained is the result of Mr. Martin's use of

24 sildenafil. This opinion is based on the history,

25 temporal relationship of sildenafil use, and the

50 (Pages 194 to 197)

| | |
|--|---|
| <p style="text-align: right;">198</p> <p>1 clinical findings of Mr. Martin's case"; do you see 2 that? 3 A. I do. 4 Q. Okay. Again, I want to go through each of 5 these. What were the clinical findings in Mr. Martin's 6 case that you made? 7 A. When I saw Mr. Martin, he was blind legally. 8 His vision was extremely poor. He had lost the -- most 9 of the vision in each eye. He -- Excuse me. I just 10 want to refer to my findings. 11 When I examined his optic nerve, he had a 12 marked optic atrophy at that time and, again, that 13 aspirin tablet nerve appearance. He had a little bit 14 of cataract, I felt not visually significant. 15 Q. Was there anything -- And, again, the clinical 16 findings for Mr. Martin confirmed the diagnosis of 17 NAION; correct? 18 A. That's correct. 19 Q. And in fact, for Mr. Martin's case, it was 20 bilateral NAION; correct? 21 A. That's correct. 22 Q. Is there anything about the clinical findings 23 in Mr. Martin's case that demonstrates that the NAION 24 was caused by sildenafil? 25 A. The clinical findings were the exam. And,</p> | <p style="text-align: right;">200</p> <p>1 Q. Okay. And you also mentioned the history. 2 What about the history of Mr. -- Mr. Martin's medical 3 history, what aspects of the history leads you to the 4 opinion that Viagra caused Mr. Martin's visual loss? 5 A. In terms of his past medical history, he had a 6 history of high blood pressure. He had the TIA, as you 7 and I mistakenly agreed to before, in May of '93. And 8 his was more recently, meaning approximately a week 9 before he treated with Catapres, which is a fairly 10 strong alpha blocker that lowers blood pressure, as 11 well as dyazide. He had smoked, but not in about 30 12 years. 13 In terms of the specific timing of the history, 14 he indicated that he took the Viagra 50 milligrams in 15 the evening on April 29th, went to sleep, and woke up 16 -- excuse me -- not woke up. I misspoke. On the next 17 day, noticed a visual loss in one eye. He called his 18 physician. He eventually saw Dr. Nichols, another 19 ophthalmologist, who is a glaucoma specialist, and 20 observed that the optic nerve on the right side was 21 swollen and that he had lost -- that -- and they did 22 appropriate diagnostic testing. He continued to lose 23 most of the vision in the right eye over the next 24 several days. 25 About a month later, he took another Viagra,</p> |
| <p style="text-align: right;">199</p> <p>1 again, that's just one part of the whole puzzle. 2 Q. Okay. 3 A. So just taking the clinical findings alone -- 4 excuse me -- the exam findings alone. You say 5 "clinical findings." I say "exam findings," and -- 6 Q. You wrote "clinical findings." That's why I'm 7 using the term. 8 A. Okay. 9 Q. If you're happy to use "exam findings," I can 10 rephrase the question. 11 A. I just -- I think "exam findings" would be -- 12 Q. Okay. 13 A. -- a little more accurate. 14 Q. Okay. I -- Like I said -- 15 A. But -- So we do just know what we're both 16 talking about. 17 Q. So let's focus on your exam findings. 18 A. Right. So the -- 19 Q. Is there anything from your exam findings that 20 demonstrates that Mr. Martin's NAION was caused by 21 sildenafil? 22 A. The exam findings show he had bilateral optic 23 atrophy and totally consistent with the history and the 24 story. But the exam alone can't be used to make that 25 specific association, yes -- yes.</p> | <p style="text-align: right;">201</p> <p>1 50 milligrams, and during the morning of the next day 2 noticed visual loss in the left eye. And he went down 3 and saw Dr. Nichols again, and then a series of -- of 4 visits and diagnostic tests and such, to save time. I 5 think it's clear. 6 Q. Now you said Mr. Martin has hypertension; 7 correct? 8 A. Yes. 9 Q. And the hypertension put him at risk for NAION; 10 correct? 11 A. To some degree, yes. 12 Q. All right. How old was Mr. Martin at the onset 13 of his eye condition -- of his NAION? 14 A. Mr. Martin was -- Let me just look. Excuse me. 15 I don't want to be inaccurate. He was born in 1933. 16 Q. In December of 1933; correct? 17 A. Right. And the visual loss was in 2002, so ... 18 Q. 68; is that right? 19 A. Yeah, almost. 20 Q. And does the age of 68 put Mr. Martin at risk 21 for NAION? 22 A. Yes. 23 Q. And as we -- And you mentioned, he had a prior 24 TIA. Does that prior TIA put Mr. Martin at risk for 25 NAION?</p> |

51 (Pages 198 to 201)

| | |
|--|--|
| <p style="text-align: right;">202</p> <p>1 A. Yes.</p> <p>2 Q. Did Mr. Martin have high cholesterol?</p> <p>3 A. He was taking -- Yes, he did. He was using</p> <p>4 Zocor.</p> <p>5 Q. Did the elevated cholesterol put Mr. Martin at</p> <p>6 risk for NAION?</p> <p>7 A. Yes.</p> <p>8 Q. Are you aware that Mr. Martin was also</p> <p>9 diagnosed with elevated blood sugars?</p> <p>10 A. I believe in 2005, they made the diagnosis of</p> <p>11 Type II diabetes.</p> <p>12 Q. And were you aware that there were tests</p> <p>13 showing elevated blood sugars as early as 2002?</p> <p>14 A. I recall there was some abnormal. I don't</p> <p>15 remember if they called it clinically diabetes or not.</p> <p>16 But it sounds reasonable.</p> <p>17 Q. Diabetes is a risk factor for NAION; correct?</p> <p>18 A. Yes.</p> <p>19 Q. Did Mr. Martin have a prior history of</p> <p>20 myocardial infarction?</p> <p>21 A. No.</p> <p>22 Q. If Mr. Martin had never -- had never taken</p> <p>23 Viagra, what would you say caused his NAION?</p> <p>24 A. I think the --</p> <p>25 MR. HOPPER: Objection; calls for hypothetical.</p> | <p style="text-align: right;">204</p> <p>1 SPECIAL MASTER BORG: Okay.</p> <p>2 (Sher Exhibit No. 14, one-page document Bates</p> <p>3 labeled MARTIN R. FERRERA 0092, was marked for</p> <p>4 identification.)</p> <p>5 BY MS. LESKIN:</p> <p>6 Q. This is Bates No. Ferrera -- Martin Ferrera 92.</p> <p>7 And you know that Dr. Ferrera was Mr. Martin's primary</p> <p>8 care physician; correct?</p> <p>9 A. That's my understanding.</p> <p>10 Q. And have you spoken to Dr. Ferrera regarding</p> <p>11 Mr. Martin?</p> <p>12 A. I have not met Dr. Ferrera or spoken to him, so</p> <p>13 ...</p> <p>14 Q. Did you review Dr. Ferrera's records about Mr.</p> <p>15 Martin prior to giving your opinion in this case?</p> <p>16 A. Yes.</p> <p>17 Q. If you look at the bottom of the document we</p> <p>18 have marked as Exhibit 12, which is Page 92 of Dr.</p> <p>19 Ferrara's records, you'll see an entry --</p> <p>20 A. I'm -- I'm -- I'm sorry. I have Exhibit 14.</p> <p>21 I'm looking at something else.</p> <p>22 Q. Oh, 14. I'm sorry. I misspoke. Wrong --</p> <p>23 wrong numbers.</p> <p>24 Start that again. If you look at the bottom of</p> <p>25 Exhibit 14, that you'll see there's an entry from Dr.</p> |
| <p style="text-align: right;">203</p> <p>1 THE WITNESS: I'm -- I'm sorry.</p> <p>2 SPECIAL MASTER BORG: It's -- it's okay,</p> <p>3 Doctor. Overruled. You may answer it if you're</p> <p>4 able.</p> <p>5 THE WITNESS: The factors that may have led</p> <p>6 hypothetically to Mr. Martin getting NAION if he</p> <p>7 didn't take them were the same factors that we have</p> <p>8 been talking about in terms of causing small blood</p> <p>9 vessel disease. I don't think he would have -- I</p> <p>10 don't think he would have had NAION had he not been</p> <p>11 taking the drug.</p> <p>12 BY MS. LESKIN:</p> <p>13 Q. And what's the basis for that opinion?</p> <p>14 A. The sum total of my analysis in this case,</p> <p>15 based on my experience and my opinions as stated here.</p> <p>16 Q. If Mr. Martin had not taken Viagra prior to the</p> <p>17 onset of his NAION, would that change your opinion in</p> <p>18 this case?</p> <p>19 A. I'm a little confused by your question, Ms.</p> <p>20 Leskin.</p> <p>21 Q. I'm going to mark as Exhibit 14 an excerpt from</p> <p>22 Dr. Ferrera's medical records.</p> <p>23 SPECIAL MASTER BORG: That would refer to who?</p> <p>24 MS. LESKIN: I'm sorry. Dr. Ferrera's medical</p> <p>25 records for Dr. -- Mr. Martin.</p> | <p style="text-align: right;">205</p> <p>1 Ferrara's records dated October 6th, 2004?</p> <p>2 A. Yes.</p> <p>3 Q. And you'll see the -- there's an S. Right? Do</p> <p>4 you see that S under the entry called S?</p> <p>5 A. Yes.</p> <p>6 Q. What does the S generally stand for?</p> <p>7 A. Subjective.</p> <p>8 Q. Okay. And you'll see where -- the sentence</p> <p>9 that starts, "He still," the fourth sentence in that</p> <p>10 paragraph?</p> <p>11 A. Yes, yes.</p> <p>12 Q. And it reads, "He still has erectile</p> <p>13 dysfunction but relates to me that he does not feel</p> <p>14 that the Viagra was given at the time he went blind."</p> <p>15 Did I read that sentence correctly?</p> <p>16 A. Yes.</p> <p>17 Q. Were you aware that Mr. Martin told his</p> <p>18 treating physician in October of 2004 that he did not</p> <p>19 feel that the Viagra was given at the time he went</p> <p>20 blind?</p> <p>21 A. I don't quite understand what he really means</p> <p>22 though.</p> <p>23 Q. Were you aware of the statement?</p> <p>24 A. I've seen the statement. I didn't really put</p> <p>25 much stock in it.</p> |

52 (Pages 202 to 205)

| | |
|---|--|
| <p style="text-align: right;">206</p> <p>1 Q. Okay. Did you read Dr. Ferrera's deposition in 2 this case?</p> <p>3 A. I did not.</p> <p>4 Q. If what Mr. Mar -- Strike that. 5 If what Dr. Ferrera wrote that Mr. Martin told 6 him is an accurate statement of fact, would that change 7 your in opinion in this case?</p> <p>8 A. Not at all.</p> <p>9 Q. If Mr. Martin had not taken Viagra prior to the 10 onset of his NAION, that would not change your opinion 11 in this case?</p> <p>12 MR. OVERHOLTZ: Object to form. Misstates the 13 document. Misstates the -- what -- his exact words. 14 It says --</p> <p>15 THE WITNESS: I'd say --</p> <p>16 MR. OVERHOLTZ: -- what Mr. Martin -- I mean if 17 you're asking for a different hypothetical, that's 18 fine. But to state it as if -- Also it's asked and 19 answered. If you're trying to say the same 20 question. It's asked and answered.</p> <p>21 THE WITNESS: I'm just sorry. Can you repeat 22 the question?</p> <p>23 MR. OVERHOLTZ: If you're trying to say a 24 different question, that's a different -- it's a 25 hypothetical.</p> | <p style="text-align: right;">208</p> <p>1 that change your opinion as to whether the Viagra 2 caused his NAION?</p> <p>3 MR. OVERHOLTZ: Same objection. "At the time" 4 is vague as to whether he meant at all or just not 5 within 24 hours, not within 48 hours, not within --</p> <p>6 MS. LESKIN: I'm reading what's in the medical 7 record, Your Honor.</p> <p>8 SPECIAL MASTER BORG: Okay. It's overruled. 9 But let's, as you do that, say -- put in your 10 question that you're reading from the medical 11 record, would you please?</p> <p>12 MR. HOPPER: But, Judge, he's or -- she's 13 asking a question based upon -- That's why this S is 14 in here. It's the self-reporting section. And he 15 just wrote down what his patient said.</p> <p>16 SPECIAL MASTER BORG: I -- I understand.</p> <p>17 MR. OVERHOLTZ: And there's no way for the 18 witnesses here or the lawyers here to speculate as 19 to what Mr. Martin could have meant at the time 20 regarding "at the time." Did he mean 24 hours?</p> <p>21 SPECIAL MASTER BORG: I -- I understand.</p> <p>22 MR. OVERHOLTZ: Did he mean 48 hours?</p> <p>23 SPECIAL MASTER BORG: I understand the 24 objection.</p> <p>25 MR. OVERHOLTZ: Okay.</p> |
| <p style="text-align: right;">207</p> <p>1 SPECIAL MASTER BORG: It's -- it's overruled. 2 Dr. Sher, do you have an answer?</p> <p>3 THE WITNESS: I just wish Ms. Leskin would 4 repeat the question, Judge.</p> <p>5 SPECIAL MASTER BORG: Okay.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. Sure. If Mr. Martin, in fact, had not taken 8 Viagra at the time of his NAION, would that change your 9 opinion in this case?</p> <p>10 MR. OVERHOLTZ: I'm -- I'm going to ask for a 11 clarification, by "did not take Viagra" whether Ms. 12 Leskin means at all, or the day before, two days 13 before, or three days before?</p> <p>14 THE WITNESS: It -- it --</p> <p>15 SPECIAL MASTER BORG: Hang on, Doctor. Would 16 you clarify that? That's fair.</p> <p>17 MS. LESKIN: I thought it was pretty clear.</p> <p>18 SPECIAL MASTER BORG: Well, it's --</p> <p>19 MS. LESKIN: I said at the time of his NAION, 20 so ...</p> <p>21 MR. OVERHOLTZ: Object; vague.</p> <p>22 THE WITNESS: He had NAION in both eyes.</p> <p>23 BY MS. LESKIN:</p> <p>24 Q. Okay. If Mr. Martin had -- If Mr. Martin had 25 not taken the Viagra at the time he went blind, does</p> | <p style="text-align: right;">209</p> <p>1 SPECIAL MASTER BORG: The document, I presume, 2 has been entered? Yes?</p> <p>3 MR. OVERHOLTZ: Yes.</p> <p>4 MS. LESKIN: Yes.</p> <p>5 SPECIAL MASTER BORG: Okay. The document says 6 what the document says. She's asking a question 7 about the document. It's overruled.</p> <p>8 MR. OVERHOLTZ: Can I make another objection?</p> <p>9 SPECIAL MASTER BORG: No.</p> <p>10 MR. OVERHOLTZ: Can I make it a foundation 11 objection as to whether this witness can even know 12 what Mr. -- Does this witness know what Mr. Martin 13 meant when he self-reported that statement?</p> <p>14 SPECIAL MASTER BORG: I think he has already 15 said that he didn't or doesn't.</p> <p>16 MR. OVERHOLTZ: Okay.</p> <p>17 SPECIAL MASTER BORG: So the objection is 18 noted, but it's overruled.</p> <p>19 MR. OVERHOLTZ: Okay.</p> <p>20 SPECIAL MASTER BORG: Ms. Leskin, how about a 21 question?</p> <p>22 BY MS. LESKIN:</p> <p>23 Q. Let me see if I can go about this a 24 different way to answers everyone's concerns.</p> <p>25 MR. OVERHOLTZ: Yeah. Let's try not tricking</p> |

53 (Pages 206 to 209)

| | |
|---|--|
| <p style="text-align: right;">210</p> <p>1 the witness and let's use some actual real</p> <p>2 questions.</p> <p>3 MS. LESKIN: I have no intention of tricking</p> <p>4 the witness.</p> <p>5 MR. OVERHOLTZ: Mmm-hmm.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. What is your understanding, Doctor, as to the</p> <p>8 temporal relationship between Mr. Martin's ingestion of</p> <p>9 Viagra and the onset of NAION in his first eye?</p> <p>10 A. There was a dose of Viagra used in Mr. Martin,</p> <p>11 and it was taken at, according to the history he gave</p> <p>12 me, the evening before. And the vision was lost in the</p> <p>13 right eye approximately at dusk the next day. He</p> <p>14 claimed it was towards evening. We have long days in</p> <p>15 Minnesota in -- in the summer. That was the temporal</p> <p>16 relationship.</p> <p>17 Q. Okay. And did you read Mr. Martin's deposition</p> <p>18 in this case?</p> <p>19 A. I did.</p> <p>20 Q. And you're aware that Mr. Martin testified that</p> <p>21 it was about 24 hours between the time of his ingestion</p> <p>22 and the time of the onset of his vision loss in that</p> <p>23 first right eye; correct?</p> <p>24 A. That's correct.</p> <p>25 Q. What is your understanding of the temporal</p> | <p style="text-align: right;">212</p> <p>1 MS. LESKIN: Yeah. I was just distracted,</p> <p>2 unfortunately.</p> <p>3 THE WITNESS: I'm sorry, Ms. Leskin.</p> <p>4 THE COURT REPORTER: Me, too.</p> <p>5 MS. LESKIN: I just want to see what the court</p> <p>6 reporter --</p> <p>7 THE COURT REPORTER: The only thing, I didn't</p> <p>8 understand what you said. You said, "And I had the</p> <p>9 impression that it was sometime in the morning or</p> <p>10 toward the" something.</p> <p>11 THE WITNESS: I'm sorry. I will just repeat</p> <p>12 it. I'm --</p> <p>13 MS. LESKIN: That's okay.</p> <p>14 THE WITNESS: Since I wrote this as close to my</p> <p>15 examination of Mr. Martin, I'm just going to go with</p> <p>16 the description. And it was based on what he told</p> <p>17 me and not what I subsequently have seen or -- you</p> <p>18 know. I just use this based on what he told me at</p> <p>19 that time. That's all I've met Mr. Martin. And</p> <p>20 that said, "During the morning of the next day, Mr.</p> <p>21 Martin noticed visual loss in the left eye."</p> <p>22 BY MS. LESKIN:</p> <p>23 Q. Okay. And to be clear, that's what Mr. Martin</p> <p>24 told you on September 4th, 2008?</p> <p>25 A. That's correct.</p> |
| <p style="text-align: right;">211</p> <p>1 relationship between the time that Mr. Martin ingested</p> <p>2 Viagra and suffered NAION in the second eye?</p> <p>3 A. It's my understanding on the second eye that he</p> <p>4 suffered -- and I don't have the exact time on the</p> <p>5 Thursday, May 30th, that he ingested Viagra at 8:00</p> <p>6 p.m. the night before, so that would be April -- excuse</p> <p>7 me -- May 29th, and that he lost vision in the left eye</p> <p>8 on Thursday, May 30th. I believe it was earlier in the</p> <p>9 day. He was driving at the time.</p> <p>10 Q. And, in fact, you wrote in your report during</p> <p>11 the morning of the next day; correct?</p> <p>12 A. Yes.</p> <p>13 Q. Well, what was the basis for your statement</p> <p>14 here "during the morning of the next day"?</p> <p>15 A. I had asked Mr. Martin at the time, I -- and I</p> <p>16 asked him to be as specific as he can, and he indicated</p> <p>17 that he was driving back from his cabin or wherever he</p> <p>18 was, and that he indicated that he had trouble reading</p> <p>19 the road signs. I just want to refer to my -- the</p> <p>20 exact description. And I had the impression that it</p> <p>21 was sometime in the morning or towards the middle of</p> <p>22 the day.</p> <p>23 MR. OVERHOLTZ: Let's take a break.</p> <p>24 MR. HOPPER: Yeah.</p> <p>25 THE WITNESS: Does that answer your question?</p> | <p style="text-align: right;">213</p> <p>1 Q. Did you read Dr. -- Mr. Martin's deposition in</p> <p>2 this case?</p> <p>3 A. This week, I looked at it, yes.</p> <p>4 Q. You'd not seen the deposition at the time you</p> <p>5 created your report in this case; correct?</p> <p>6 A. No. I was not sent it.</p> <p>7 Q. Are you aware --</p> <p>8 MR. HOPPER: It's part lawyers.</p> <p>9 THE WITNESS: What?</p> <p>10 BY MS. LESKIN:</p> <p>11 Q. Are you aware that Mr. Martin testified -- and</p> <p>12 I'm referring to Page 172 of his deposition</p> <p>13 transcript --</p> <p>14 A. I -- I don't -- I don't have it. I'm going to</p> <p>15 have to see it. I'm sorry.</p> <p>16 Q. Okay. Would you like to see it?</p> <p>17 A. If you're going to ask me questions about it --</p> <p>18 Q. Sure.</p> <p>19 A. -- yes, please.</p> <p>20 MS. LESKIN: Do you have some extra copies?</p> <p>21 MS. FYMAN: Yeah, they're right in front of</p> <p>22 you.</p> <p>23 MS. LESKIN: Okay.</p> <p>24 THE VIDEOGRAPHER: We have three minutes to</p> <p>25 tape change.</p> |

54 (Pages 210 to 213)

| | |
|--|--|
| <p style="text-align: right;">214</p> <p>1 (Sher Exhibit No. 15, 55-page document entitled</p> <p>2 Deposition of Richard Martin taken August 5, 2008,</p> <p>3 was marked for identification.)</p> <p>4 BY MS. LESKIN:</p> <p>5 Q. Okay. This won't take that -- Marking as</p> <p>6 Exhibit 15, a copy of the transcript for Mr. Martin's</p> <p>7 deposition dated August 5th, 2008. And I'll ask you</p> <p>8 turn to Page 172 of the transcript. Are you with me?</p> <p>9 A. Yeah.</p> <p>10 Q. Do you see on Line 3 of that page, I asked a</p> <p>11 question, "When did you first start having problems in</p> <p>12 your left eye?" And you know that that left eye is the</p> <p>13 second eye; correct?</p> <p>14 A. Yes. Are we looking -- I'm sorry. You said</p> <p>15 Page 172?</p> <p>16 Q. Page 172, Line 3.</p> <p>17 A. Okay. "When we were coming back -- you mean</p> <p>18 the date?"</p> <p>19 Q. That was his answer.</p> <p>20 MR. HOPPER: That's Line 5.</p> <p>21 BY MS. LESKIN:</p> <p>22 Q. That's Line 5. That's the answer to my</p> <p>23 question; right?</p> <p>24 A. Yes.</p> <p>25 Q. The question -- Do you see it just says "Q"?</p> | <p style="text-align: right;">216</p> <p>1 (A short break was held from 1:58 p.m. to 2:09</p> <p>2 p.m.)</p> <p>3 THE VIDEOGRAPHER: For identification, this is</p> <p>4 the beginning of Videotape 3. The time is 2:09 p.m.</p> <p>5 We are now back on the video record.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. Doctor, before the break, we were talking about</p> <p>8 the temporal relationship between Mr. Martin's use of</p> <p>9 Viagra and the onset of his NAION. Do you recall we</p> <p>10 were in that -- the middle of that discussion?</p> <p>11 A. Yes.</p> <p>12 Q. Now if Mr. Martin had not taken Viagra the</p> <p>13 evening before he noticed the loss of vision in his</p> <p>14 right eye, does that change your opinion as to whether</p> <p>15 Viagra caused the loss of vision in that right eye?</p> <p>16 A. No.</p> <p>17 Q. And if Mr. Martin had not taken Viagra the</p> <p>18 night before the loss of vision in his left eye, would</p> <p>19 that change your opinion as to whether Viagra caused</p> <p>20 his loss of vision in that left eye?</p> <p>21 A. No.</p> <p>22 Q. Is there a time frame between the ingestion of</p> <p>23 Viagra and the loss of vision that would be too much</p> <p>24 for you to be able to create a causal relationship</p> <p>25 between the two?</p> |
| <p style="text-align: right;">215</p> <p>1 A. Yes, yes.</p> <p>2 Q. And I asked, "When did you first start having</p> <p>3 problems in your left eye?"</p> <p>4 And the answer was, "When we were coming back,</p> <p>5 you mean the date?"</p> <p>6 I said, "Yes."</p> <p>7 He said, "It was about a month later."</p> <p>8 And I said, "Yes."</p> <p>9 And then he described -- he described the drive</p> <p>10 from the cabin; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And then that second paragraph at Line 19, and</p> <p>13 he says, "And then I looked at the billboard, and I</p> <p>14 could only see half the billboard. And I told her --</p> <p>15 and this was about 8 o'clock at night, and I said,</p> <p>16 'We're going to have to see the doctor again in the</p> <p>17 morning, because I think my eye's going bad.' And it</p> <p>18 started losing vision in my left eye."</p> <p>19 When you read Dr. -- Mr. Martin's transcript</p> <p>20 this week, did you notice that statement?</p> <p>21 A. I did.</p> <p>22 SPECIAL MASTER BORG: Tape?</p> <p>23 MS. LESKIN: Change the tape?</p> <p>24 THE VIDEOGRAPHER: For identification, this is</p> <p>25 the end of Videotape 2. The time is 1:58 p.m.</p> | <p style="text-align: right;">217</p> <p>1 A. I understand the half-lives of Viagra and</p> <p>2 the -- the action. I think that beyond 48 hours would</p> <p>3 make me less. Patient's reporting, however, sometimes</p> <p>4 is just inaccurate. And as we extensively talked about</p> <p>5 before, Ms. Leskin, their reporting of their visual</p> <p>6 loss is a little bit inaccurate frequently. So I would</p> <p>7 say beyond 48 hours would bother me.</p> <p>8 Q. Do you know when the swelling of the optic</p> <p>9 nerve in Mr. Martin's right eye began?</p> <p>10 A. No.</p> <p>11 Q. Do you know when the swelling in Mr. Martin's</p> <p>12 left eye began?</p> <p>13 A. No.</p> <p>14 Q. And do you know the relationship between the</p> <p>15 beginning of the swelling of either optic nerve and the</p> <p>16 ingestion of Viagra?</p> <p>17 A. No.</p> <p>18 Q. In -- in preparing your expert report in these</p> <p>19 cases, did you look at any of the studies that had been</p> <p>20 done on ocular circulation following use of sildenafil?</p> <p>21 A. I did.</p> <p>22 Q. Did you find any study that demonstrated that</p> <p>23 Viagra decreases blood flow to any vessel in the eye?</p> <p>24 A. The studies were mostly done in animals, and</p> <p>25 there were some humans. In general, when we talk about</p> |

55 (Pages 214 to 217)

| | |
|---|---|
| <p style="text-align: right;">218</p> <p>1 blood flow in the eye, we have to distinguish really 2 what part of the eye. The -- Most of the studies were 3 done on healthy volunteers, and they looked at flow in 4 the retinal artery and some blood flow in the retina. 5 I could not find any study that would convincingly show 6 me one way or the other what happened to the flow in 7 the posterior ciliary little tiny twigs and vessels 8 that are responsible here. So there's lots of studies. 9 Unfortunately, none of them, I think, have a lot of 10 relevance. 11 I also feel that taking Viagra doesn't 12 necessarily diminish blood flow to those parts of the 13 eye that we just mentioned, as we said this morning. 14 It may actually increase the flow in the retinal artery 15 which then pushes and squeezes that essential retinal 16 vein and causes some of those problems. 17 I think the real issue with Viagra is its parts 18 not so much directly on the eye, but what it does to 19 the rest of the body in that -- that it dilates blood 20 vessels and that blood pools, particularly at night, 21 and it causes arterial hypotension. 22 MS. LESKIN: Objection; non-responsive. 23 SPECIAL MASTER BORG: Sustained. 24 BY MS. LESKIN: 25 Q. Are you aware of any study that demonstrates</p> | <p style="text-align: right;">220</p> <p>1 an excerpt from the deposition of Dr. Gerald McGwin 2 taken on December 11th, 2008. 3 (Sher Exhibit No. 16, three-page document, an 4 excerpt from the videotaped deposition of Dr. Gerald 5 D. McGwin, Jr., was marked for identification.) 6 BY MS. LESKIN: 7 Q. And I agree this is not the entire deposition, 8 but this is a few pages of it. And if I recall your 9 testimony correctly, you have not seen this deposition 10 transcript before; is that correct? 11 A. No, I haven't. 12 Q. Okay. 13 A. That's correct. That's correct. 14 Q. I'd like to direct your attention to the second 15 page of the exhibit, Exhibit 16, which starts at Page 16 327 of the transcript. Are you with me? 17 A. Yes. 18 Q. Okay. And if you look at Line 6, and the 19 question was asked, "Take a look at Table Number 25 -- 20 at Exhibit Number 25. And that's the electronic data 21 set that you marked where there were inconsistencies. 22 And let's focus on the Viagra exposure variable. You 23 indicated that there were three cases that were coded 24 as exposed where the records were inconsistent with 25 exposure; correct?"</p> |
| <p style="text-align: right;">219</p> <p>1 Viagra decreases blood flow to any ocular vessel? 2 A. I don't think that the real stu -- I'm not 3 aware of every study of Viagra on blood vessels. I 4 know the animal studies, the model is just a poor 5 model, and basically, I think don't apply. 6 I do think that Viagra increases blood flow to 7 certain parts of the eye. Unfortunately, not the parts 8 that these gentlemen needed. 9 MS. LESKIN: Objection; non-responsive. 10 SPECIAL MASTER BORG: Sustained. 11 BY MS. LESKIN: 12 Q. Are you aware of any study that demonstrates 13 that Viagra decreases blood flow to any vessel in the 14 eye? 15 MR. HOPPER: If you know. 16 THE WITNESS: I don't know. 17 BY MS. LESKIN: 18 Q. You're not aware of any? 19 A. I'm not aware. 20 Q. Doctor, we were talking earlier about Dr. 21 McGwin's study. 22 A. Yes, ma'am. 23 Q. Do you recall that conversation? 24 A. Some of it. 25 Q. Okay. I'm going to mark as Exhibit 16, this is</p> | <p style="text-align: right;">221</p> <p>1 "Answer: Yes, sir." 2 "And so if the number -- if the data had been 3 coded consistently with the manuscript, the number 4 in Table 2 for exposed cases of Viagra would go from 5 14 to 11; is that right?" 6 And then he -- there's some colloquy about 7 whether he can write on the document. And then the 8 question is asked again, "So, in other words, on 9 Table 2 where you have a Number 14, that would go 10 down to 11?" 11 "Answer: Assuming that these are, in fact, 12 errors." 13 "Question: That's right. Based on the 14 exposure in the -- the exposure definition in the 15 manuscript and the records that we have looked at 16 today; correct?" 17 "Answer: With those assumptions, yes, sir." 18 Were you aware that Dr. McGwin gave that 19 testimony on December 11th, 2008? 20 A. I wasn't given Dr. McGwin's testimony, so by 21 definition, I was unaware. 22 Q. No one summarized that for you? 23 A. No. 24 Q. Okay. Going back to the questions we were 25 talking about before. I want you to assume</p> |

56 (Pages 218 to 221)

| | |
|--|--|
| <p style="text-align: right;">222</p> <p>1 hypothetically --</p> <p>2 MR. HOPPER: I'm sorry; which questions before?</p> <p>3 BY MS. LESKIN:</p> <p>4 Q. Okay. Strike the intro.</p> <p>5 I want you to assume hypothetically that the</p> <p>6 authors of the McGwin study did not count exposed cases</p> <p>7 as represented in the article, but that they also</p> <p>8 counted as exposed cases people who were diagnosed with</p> <p>9 NAION before they ever took Viagra. If that were true,</p> <p>10 would that make the findings of the study unreliable?</p> <p>11 MR. HOPPER: Objection; calls for a</p> <p>12 hypothetical.</p> <p>13 SPECIAL MASTER BORG: It's overruled.</p> <p>14 If you're able to answer it, Doctor.</p> <p>15 MR. HOPPER: If you understand it.</p> <p>16 THE WITNESS: I'm not able to rule it. I don't</p> <p>17 have details of the nitty-gritty of how Mr. Mc --</p> <p>18 Dr. McGwin called people and got the information. I</p> <p>19 know roughly. So I'm just not in a position to --</p> <p>20 to answer that.</p> <p>21 BY MS. LESKIN:</p> <p>22 Q. And if you assume hypothetically that, as Dr.</p> <p>23 McGwin testified, the authors miscounted, and that only</p> <p>24 11, rather than 14 of the 38 cases in the study had</p> <p>25 been exposed to Viagra, would that make the published</p> | <p style="text-align: right;">224</p> <p>1 record. The time is 2:35 p.m.</p> <p>2 BY MS. LESKIN:</p> <p>3 Q. Dr. Sher, we're almost done.</p> <p>4 A. Thank God.</p> <p>5 Q. I'd like to take your attention back to Exhibit</p> <p>6 12, which is the log of time you spent with Zimmerman</p> <p>7 Reed.</p> <p>8 MR. HOPPER: Sorry. I wasn't laughing at you.</p> <p>9 I was laughing at something I wrote.</p> <p>10 THE WITNESS: Can I -- Did you want me to look</p> <p>11 at something?</p> <p>12 MS. LESKIN: Do you -- do you have your copy</p> <p>13 here?</p> <p>14 THE WITNESS: Mmm-hmm. I think so.</p> <p>15 MR. HOPPER: You didn't put that in there --</p> <p>16 onomatopoeia in there, I hope. I was looking at</p> <p>17 something I wrote earlier this morning.</p> <p>18 MR. OVERHOLTZ: Onomatopoeia?</p> <p>19 MR. HOPPER: I didn't write "onomatopoeia." I</p> <p>20 just -- It just was expressed in onomatopoeia.</p> <p>21 MR. OVERHOLTZ: Oh, you did?</p> <p>22 MR. HOPPER: Can you spell it?</p> <p>23 MR. OVERHOLTZ: Mmm-hmm.</p> <p>24 MS. LESKIN: Counsel?</p> <p>25 THE WITNESS: Your question?</p> |
| <p style="text-align: right;">223</p> <p>1 findings unreliable?</p> <p>2 A. I can't answer that. I -- I just don't -- I'm</p> <p>3 not a statistician, and it would call for a statistical</p> <p>4 answer.</p> <p>5 Q. What percentage of Mr. Martin's NAION is</p> <p>6 attributable to Viagra?</p> <p>7 A. That's a hypothetical that would be difficult</p> <p>8 to answer. But it would be 100 percent, because my</p> <p>9 opinion would be that he wouldn't have it if it wasn't</p> <p>10 for taking the drug.</p> <p>11 Q. And what percentage of Mr. Stanley's NAION is</p> <p>12 attributable to Viagra?</p> <p>13 A. Same answer.</p> <p>14 MS. LESKIN: You know what? I need a few</p> <p>15 minutes just to go through my paperwork. I may be</p> <p>16 just about done.</p> <p>17 SPECIAL MASTER BORG: Yeah. Okay.</p> <p>18 THE VIDEOGRAPHER: We're going off the record?</p> <p>19 MS. LESKIN: Yeah.</p> <p>20 THE VIDEOGRAPHER: We're now going off the</p> <p>21 video record. The time is 2:20 p.m.</p> <p>22 SPECIAL MASTER BORG: Five minutes.</p> <p>23 (A short break was held from 2:21 p.m. to 2:35</p> <p>24 p.m.)</p> <p>25 THE VIDEOGRAPHER: We are now back on the video</p> | <p style="text-align: right;">225</p> <p>1 BY MS. LESKIN:</p> <p>2 Q. Okay. Looking at Exhibit 12. I'm looking at</p> <p>3 the second page, and there's a bunch of dates here in</p> <p>4 February of 2009.</p> <p>5 A. This week, yeah.</p> <p>6 Q. That's right. And it says, "Reviewed Wein --</p> <p>7 Weingarden, Gartner, Stanley, Martin, Nichols, Bhavsar,</p> <p>8 the depositions, Hayreh deposition?"</p> <p>9 A. Yes.</p> <p>10 Q. You understand those are the depositions of the</p> <p>11 treating physicians and the experts in this case;</p> <p>12 right?</p> <p>13 A. That's correct.</p> <p>14 Q. Do I read your time records correctly that you</p> <p>15 did not read those depositions prior to writing your</p> <p>16 report?</p> <p>17 A. That's correct.</p> <p>18 Q. Did you review the deposition of Dr. Andrew Lee</p> <p>19 in this case?</p> <p>20 A. Yes. I think one or two nights ago. He's from</p> <p>21 Iowa.</p> <p>22 Q. Correct.</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And you are aware then that Dr. Lee did</p> <p>25 not give an expert opinion in the Stanley case;</p> |

57 (Pages 222 to 225)

| | |
|---|---|
| <p style="text-align: right;">226</p> <p>1 correct?</p> <p>2 A. I think he just opined about Mr. Martin, but I</p> <p>3 could be wrong.</p> <p>4 MR. HOPPER: If you recall.</p> <p>5 THE WITNESS: I don't recall.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. Do you recall that Dr. Lee testified he did not</p> <p>8 believe the Stanley case was a strong enough case to</p> <p>9 establish causation?</p> <p>10 A. I don't recall.</p> <p>11 Q. I want to go back to the Martin case and your</p> <p>12 opinion on Mr. Martin.</p> <p>13 A. Yes.</p> <p>14 Q. If you look at the second page of your report,</p> <p>15 you have a statement there that says under the first</p> <p>16 paragraph, History of Sildenafil Use. Do you see where</p> <p>17 I am?</p> <p>18 A. Yes.</p> <p>19 Q. And that first sentence says, "He began taking</p> <p>20 sildenafil soon after the drugs were released to the</p> <p>21 public in 2000." Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know when Viagra was actually released</p> <p>24 to the market?</p> <p>25 A. 1998.</p> | <p style="text-align: right;">228</p> <p>1 retinal detachment in June of 2000; correct?</p> <p>2 A. Yes.</p> <p>3 Q. And he underwent scleral buckle surgery;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And that was about three months before the</p> <p>7 onset of his NAION?</p> <p>8 A. That's correct.</p> <p>9 Q. Are you aware of reports associating NAION with</p> <p>10 scleral buckle surgery?</p> <p>11 A. There are no convincing reports. And I believe</p> <p>12 Dr. Bhavsar -- who I respect as a retinal expert. I</p> <p>13 know him. He's quite well-respected -- says that</p> <p>14 there's no association in this case between Mr.</p> <p>15 Stanley's surgery and the NAION.</p> <p>16 Q. Did you read Dr. Bhavsar's deposition testimony</p> <p>17 in this case?</p> <p>18 A. Yes, I did.</p> <p>19 Q. Are you aware that Dr. Bhavsar testified that</p> <p>20 he did not believe the association between Viagra and</p> <p>21 NAION had been established?</p> <p>22 A. He said that, yes. He also --</p> <p>23 Q. "Yes"?</p> <p>24 A. Yes.</p> <p>25 MS. LESKIN: Nothing further.</p> |
| <p style="text-align: right;">227</p> <p>1 Q. And do you know when Mr. Martin started taking</p> <p>2 Viagra?</p> <p>3 A. He told me, at least my history was that he</p> <p>4 started taking it in 2000. But he might have been</p> <p>5 mistaken.</p> <p>6 Q. Did you --</p> <p>7 A. It might have been earlier.</p> <p>8 Q. Did you see the notations on his medical</p> <p>9 records indicating that he started taking it in 1998?</p> <p>10 A. I just wrote down here what -- what he</p> <p>11 indicated. But I --</p> <p>12 Q. When you -- when you met with him?</p> <p>13 A. I -- I don't -- I don't dispute -- Yeah. When</p> <p>14 he -- I met with him, he said 2000. When I prepared</p> <p>15 for this deposition, I saw that it was probably</p> <p>16 earlier. I wrote that -- this down at the time based</p> <p>17 on what he told me.</p> <p>18 Q. Do you know how many times Mr. Martin had taken</p> <p>19 Viagra prior to the onset of his ischemic optic</p> <p>20 neuropathy for the first eye?</p> <p>21 A. I believe he said he used it once a week, so</p> <p>22 I -- I don't know how many times total, Ms. Leskin.</p> <p>23 Q. Turn to Mr. Stanley's report, please.</p> <p>24 A. Yes.</p> <p>25 Q. You make note here that Mr. Stanley had a</p> | <p style="text-align: right;">229</p> <p>1 MR. OVERHOLTZ: All right. We have just a few</p> <p>2 minutes, I think.</p> <p>3 SPECIAL MASTER BORG: Yes.</p> <p>4 MR. OVERHOLTZ: 10, 15 maybe.</p> <p>5 SPECIAL MASTER BORG: Okay. Do you want a</p> <p>6 break, or do you want to go ahead and --</p> <p>7 MR. OVERHOLTZ: I'm good to go.</p> <p>8 THE WITNESS: I'm ready.</p> <p>9 MR. OVERHOLTZ: I may need a break to try to</p> <p>10 collect my thoughts when I get to the end, but ...</p> <p>11 SPECIAL MASTER BORG: Okay. That's fine.</p> <p>12 CROSS-EXAMINATION</p> <p>13 BY MR. OVERHOLTZ:</p> <p>14 Q. Are you ready, Doctor?</p> <p>15 A. I am. Please.</p> <p>16 Q. Okay. Dr. Sher, you are a practicing</p> <p>17 ophthalmologist?</p> <p>18 A. I am.</p> <p>19 Q. And does that mean that you see patients?</p> <p>20 A. I do.</p> <p>21 Q. And how long have you been doing that?</p> <p>22 A. Since 1979, '80.</p> <p>23 Q. And you see patients with a wide range of</p> <p>24 ocular disease?</p> <p>25 A. I do.</p> |

58 (Pages 226 to 229)

| | |
|--|--|
| <p style="text-align: right;">230</p> <p>1 Q. Okay. Could you briefly describe for me -- we 2 have your CV as one of the exhibits to the 3 deposition -- but could you briefly describe your 4 educational history, including your medical education 5 and then maybe your -- some of your history as a 6 practicing ophthalmologist?</p> <p>7 A. I graduated college and medical school at 8 Boston University. After that, I came out to 9 University of Minnesota for pediatric training. I then 10 went into the public health service where I did 11 research in immunology and was assigned to the Food and 12 Drug Administration Division of Bureau of Biologics 13 which was on the NIH campus. I spent three years doing 14 that.</p> <p>15 I decided that I wanted to pursue 16 ophthalmology. I got interested in at that time in my 17 research. I came back to Minnesota where I knew the 18 people, finished residency there, then went to London 19 for a six-month fellowship in corneal surgery. And 20 then I entered private practice with two other 21 excellent ophthalmologists in Minneapolis after that 22 time.</p> <p>23 Q. Okay. And in your practice today, when you see 24 patients with eye disease or ocular disease, do you 25 attempt for most patients to make a diagnosis?</p> | <p style="text-align: right;">232</p> <p>1 research, speak to colleagues, gain consultation, if 2 that's necessary from another colleague, and reach -- 3 reach the conclusion, Mr. Overholtz.</p> <p>4 Did that answer your question?</p> <p>5 Q. It did. And do you also -- Do you occasionally 6 consult patients', maybe their previous medical records 7 or ocular records?</p> <p>8 A. Absolutely. I try to get them whenever they're 9 relevant.</p> <p>10 Q. Okay. And what about a review of a patient's 11 medications? Is that part of the metho -- methodology 12 you would use?</p> <p>13 A. I do. We always ask the patients their 14 medicines. And if I'm suspicious, I really drill down 15 and say exactly -- ask them what they're taking or ask 16 them to bring them in and let me look at the bottles.</p> <p>17 Q. And are you -- are you aware of The Annals of 18 Diagnostic Medicine?</p> <p>19 A. Are you talking about a journal?</p> <p>20 Q. A journal. Yeah.</p> <p>21 A. I've heard the name. I'm not -- I'm sorry.</p> <p>22 Q. Let me ask you this: This methodology --</p> <p>23 A. Yes.</p> <p>24 Q. -- that you've described in making a diagnosis, 25 do you believe that this is the generally-accepted</p> |
| <p style="text-align: right;">231</p> <p>1 A. Yes.</p> <p>2 Q. Can you describe for me the scientific 3 methodology that you employ as a practicing 4 ophthalmologist to diagnose a -- a patient who comes in 5 with some type of ocular disease or vision loss?</p> <p>6 A. Yes, we -- Ophthalmologists are -- are 7 physicians. Lots of people don't know that. And we're 8 scien -- and we try to be -- follow the scientific 9 method and use generally-accepted principles of both 10 science and medicine.</p> <p>11 So when a patient would come in, we would, to 12 be brief, take a history, look -- examine the patient, 13 find the likely cause of their issue -- of -- of the 14 problem, and to make a diagnosis or make a differential 15 diagnosis, a number of things that -- that something 16 could be, and gather -- and gather other facts. And 17 use generally-accepted principles of medicine and 18 science to -- to come up with a diagnosis and treat 19 them.</p> <p>20 Q. Okay. And that methodology you use, would that 21 involve a review of medical literature or texts, if 22 necessary?</p> <p>23 A. Yes. In -- in -- in cases that are more 24 challenging where one needs to do medical literature, 25 you just -- you use your knowledge, medical literature,</p> | <p style="text-align: right;">233</p> <p>1 methodology that other ophthalmologists use in 2 diagnosis of their patients?</p> <p>3 A. I think it's the accepted methodology that 4 ophthalmologists and all physicians follow.</p> <p>5 Q. Dr. Sher, sometimes as a clinical practicing 6 ophthalmologist, is it important for you to make a 7 determination of the etiology or the cause of a 8 patient's disease of the eye or their eye injury?</p> <p>9 A. It is. Because, one, we want to know, and two, 10 we want to prevent it from happening either to them or 11 someone else.</p> <p>12 Q. Can determining the cause of a patient's ocular 13 disease help you make -- determine treatment choices, 14 if any?</p> <p>15 A. Absolutely.</p> <p>16 THE VIDEOGRAPHER: Excuse me. Somebody's -- 17 somebody's wiping me completely off the audio with 18 a -- with a cell phone or something, Blackberry.</p> <p>19 THE WITNESS: It's not mine.</p> <p>20 THE VIDEOGRAPHER: It -- it just went off. But 21 that last question and answer series I did not get 22 it clearly on the audio or the video.</p> <p>23 MR. OVERHOLTZ: I'm off.</p> <p>24 THE VIDEOGRAPHER: Okay.</p> <p>25 MS. LESKIN: I'm off.</p> |

59 (Pages 230 to 233)

| | |
|--|---|
| <p style="text-align: right;">234</p> <p>1 SPECIAL MASTER BORG: Just ask it again --</p> <p>2 MR. OVERHOLTZ: All right.</p> <p>3 SPECIAL MASTER BORG: -- unless you have a</p> <p>4 record.</p> <p>5 MS. LESKIN: Can you read it?</p> <p>6 THE COURT REPORTER: I can read it.</p> <p>7 SPECIAL MASTER BORG: Let's go on.</p> <p>8 MR. OVERHOLTZ: All right.</p> <p>9 BY MR. OVERHOLTZ:</p> <p>10 Q. I was asking you, Doctor, about the reasons why</p> <p>11 it would be important to sometimes determine a cause or</p> <p>12 etiology of a patient's disease. Can you describe for</p> <p>13 me the -- the scientific methodology you would use in</p> <p>14 determining the cause or the etiology of a patient's</p> <p>15 ocular disease or if it's any different from what you</p> <p>16 just described?</p> <p>17 A. Well, you need to take the history from the</p> <p>18 patient carefully.</p> <p>19 Q. Okay.</p> <p>20 A. You need to find out all the factors, what's</p> <p>21 going on socially and environmentally. If -- you know</p> <p>22 -- someone comes in with an itchy eye, they may have</p> <p>23 used a new perfume or something. We need to look at</p> <p>24 all the medical records. We need -- that we -- that</p> <p>25 are available. It isn't a perfect world. They're not</p> | <p style="text-align: right;">236</p> <p>1 Q. Is -- is that because you -- it's your</p> <p>2 understanding that a patient is relying on you to</p> <p>3 provide the best information possible about their</p> <p>4 problem?</p> <p>5 MS. LESKIN: Objection; leading.</p> <p>6 SPECIAL MASTER BORG: I'm sorry?</p> <p>7 MS. LESKIN: Objection; leading.</p> <p>8 SPECIAL MASTER BORG: Oh, overruled.</p> <p>9 MR. HOPPER: He gets to.</p> <p>10 SPECIAL MASTER BORG: Overruled.</p> <p>11 MS. LESKIN: On his own witness?</p> <p>12 THE WITNESS: We try our best. I'm sorry. You</p> <p>13 distracted me. We try to do the best job we can</p> <p>14 with each of our patients to help -- to help them.</p> <p>15 That's -- that's our goal and that's our obligation.</p> <p>16 And that means coming up with the best diagnosis,</p> <p>17 coming up with the etiology, and trying to treat</p> <p>18 them.</p> <p>19 BY MR. OVERHOLTZ:</p> <p>20 Q. Doctor, sometimes when you make a determination</p> <p>21 of the cause of someone's ocular disease, do you have</p> <p>22 to make that determination so that you can make the</p> <p>23 best treatment decision even though there may not be</p> <p>24 complete agreement in the medical community regarding</p> <p>25 the issues involved?</p> |
| <p style="text-align: right;">235</p> <p>1 always available. And we need to then combine that</p> <p>2 with our examination of the patients. And with the sum</p> <p>3 total of our medical knowledge and scientifically and</p> <p>4 reasonably and logically put it all together and come</p> <p>5 up with a diagnosis and an etiology.</p> <p>6 Q. As you described before in making a diagnosis,</p> <p>7 you might look at medical literature or texts, if</p> <p>8 necessary?</p> <p>9 A. I would, yes.</p> <p>10 Q. Okay. Would you engage ever in a differential</p> <p>11 diagnosis-type procedure?</p> <p>12 A. If I wasn't a hundred percent sure of one</p> <p>13 diagnosis, I might put down in order the most likely</p> <p>14 and write "rule out this" or "rule out that." I</p> <p>15 usually might put "unlikely" in parentheses for that</p> <p>16 just so I can go back and others can look at my records</p> <p>17 and know what my thinking was at the time.</p> <p>18 Q. And in applying this methodology, you then</p> <p>19 attempt to try to make a determination of the etiology</p> <p>20 or cause of the disease?</p> <p>21 A. Yes, sir.</p> <p>22 Q. When you make such determinations about a</p> <p>23 patient's disease, do you try to do so to a reasonable</p> <p>24 degree of medical probability?</p> <p>25 A. Yes.</p> | <p style="text-align: right;">237</p> <p>1 A. Yes.</p> <p>2 Q. So -- When it comes to caring for patients and</p> <p>3 making determinations about their disease, the cause</p> <p>4 and -- do you have to look at all the available</p> <p>5 evidence -- evidence and then exercise your clinical</p> <p>6 judgment?</p> <p>7 A. It's -- We try to be open-minded, look at</p> <p>8 everything, be scientific, not be biased, and make the</p> <p>9 best judgment using our knowledge and experience.</p> <p>10 Q. And so when you say "using clinical judgment,"</p> <p>11 do you mean to look at all the available evidence</p> <p>12 that's available about a particular patient or issue</p> <p>13 and make the best determination?</p> <p>14 A. I think that's a fair description, yes, sir.</p> <p>15 Q. This methodology that we've gone through that</p> <p>16 you would apply in trying to determine the etiology or</p> <p>17 cause of the patient's ocular disease, is it your</p> <p>18 understanding that that's the generally-accepted</p> <p>19 methodology that other ophthalmologists would apply?</p> <p>20 A. It is.</p> <p>21 Q. I want to ask you a few questions about these</p> <p>22 two cases that you've been asked to serve as an expert</p> <p>23 in; okay?</p> <p>24 A. Yes, sir.</p> <p>25 Q. In Mr. Martin's case, you were asked to make a</p> |

60 (Pages 234 to 237)

| | |
|---|--|
| <p style="text-align: right;">238</p> <p>1 determination of the diagnosis of Mr. Martin's vision 2 loss? 3 A. Yes. 4 Q. And were you also asked to make a determination 5 as to the etiology or the cause of Mr. Martin's vis -- 6 vision loss? 7 A. Yes. 8 Q. And did you also -- Were you asked to make 9 those same determinations regarding the diagnosis and 10 the cause of Mr. Stanley's vision loss? 11 A. Yes, sir. 12 Q. Okay. Is it your opinion to a reasonable 13 degree of medical probability that Mr. Martin's vision 14 loss was most likely NAION as a result -- it was NAION 15 and was as a result of his use of Viagra? 16 A. It is. And it is my opinion. 17 Q. Okay. And is it your opinion to a reasonable 18 degree of medical probability that Viagra was more 19 likely than not a significant contributing factor in 20 Mr. Martin's NAION? 21 A. I -- I agree with that statement. Viagra was a 22 significant contributing factor in Mr. Martin's 23 blindness. 24 Q. Okay. And let me ask you those opinions that 25 you have regarding Mr. Martin's vision loss, is it your</p> | <p style="text-align: right;">240</p> <p>1 practice that I use in my practice to treat patients 2 and to make sound medical and scientific judgments. 3 Q. All right. One of the steps that you described 4 in this methodology was your review of relevant medical 5 literature. Do you recall that? 6 A. Yes, sir. 7 Q. With that in mind, do you recall Counsel's 8 questions regarding your reliance on certain pieces of 9 medical literature? 10 A. Is there any particular -- 11 Q. In other words, asking you specifically -- 12 A. Yes. 13 Q. -- about one piece of medical literature or 14 another article? 15 A. Yes. Correct. 16 Q. In reaching your opinions in this case or in 17 your general treatment of patients, do you ever rely on 18 one single study in forming your opinions? 19 A. No. 20 Q. And what do you do instead? 21 A. I take the totality of the evidence, weigh the 22 quality of the studies, weigh the -- the evidence, 23 and -- and make my decision. 24 MR. OVERHOLTZ: Okay. That's all I have. 25 SPECIAL MASTER BORG: Ms. Leskin, anything?</p> |
| <p style="text-align: right;">239</p> <p>1 opinion to a reasonable degree of medical probability 2 that Mr. Stanley's vision loss was most likely NAION as 3 a result of his use of Viagra? 4 A. Yes, it is. 5 Q. And is it your opinion to a reasonable degree 6 of medical probability that Viagra was more likely than 7 not a significant contributing factor to Mr. Stanley's 8 development of NAION? 9 A. It is my opinion. 10 Q. And the opinions that you've stated today in 11 this deposition, do you hold those opinions -- all of 12 those opinions to a reasonable degree of medical 13 probability? 14 A. I do. 15 Q. And does that include the opinions that you've 16 given in your report? 17 A. Yes. 18 Q. Couple more questions, Dr. Sher, and then we'll 19 be finished. 20 In reaching the opinions that you've reached 21 regarding Mr. Martin and Mr. Stanley's vision loss, did 22 you apply the same methodology that you testified you 23 would use in your practice as a treating clinical 24 ophthalmologist? 25 A. I did. I used all the same principles and</p> | <p style="text-align: right;">241</p> <p>1 REDIRECT-EXAMINATION 2 BY MS. LESKIN: 3 Q. I have one question. You just said that you 4 look at the studies and the quality of the studies? 5 A. Yes. 6 Q. Other than Dr. McGwin's paper, what studies did 7 you rely on in reaching your conclusion here today? 8 A. I think I answered that before for you, but the 9 literally dozens and dozens of articles concerning 10 NAION, concerning physiology of -- of how these drugs 11 work, and all the information that I discussed with you 12 before were relied on. 13 Q. I don't -- Now you said dozens and dozens of 14 articles. 15 A. That's correct. 16 Q. I'm asking specifically which studies? 17 MR. HOPPER: I'm going to -- 18 BY MS. LESKIN: 19 Q. Which of those articles were studies that you 20 relied on, that you looked at in reaching your opinion? 21 A. There -- there are -- 22 MR. HOPPER: I will enter an objection of asked 23 and answered. That's one -- hours ago -- 24 MR. OVERHOLTZ: I'm going to object that she's 25 attempting to change the witness's testimony. He</p> |

61 (Pages 238 to 241)

| | |
|--|--|
| <p style="text-align: right;">242</p> <p>1 says he didn't rely on one specific study. He</p> <p>2 relied on all the studies that he looked at.</p> <p>3 MS. LESKIN: And I'm asking what studies.</p> <p>4 SPECIAL MASTER BORG: I understand the</p> <p>5 question. It's overruled.</p> <p>6 BY MS. LESKIN:</p> <p>7 Q. Which of the articles that you relied on are</p> <p>8 studies?</p> <p>9 A. I -- I don't -- Would you define a "study" for</p> <p>10 me versus an "article," because I don't understand your</p> <p>11 question.</p> <p>12 Q. Okay. Well, you said that you looked at the</p> <p>13 quality of the studies. So how do you define "studies"</p> <p>14 when you use that term?</p> <p>15 A. I use them interchangeably.</p> <p>16 Q. So anything that's published as an article in</p> <p>17 your head -- in your mind is also a study for purposes</p> <p>18 of your testimony here today?</p> <p>19 A. Well, to be more precise, a study may have a</p> <p>20 specific goal in mind where someone gets Drug A or</p> <p>21 someone gets Placebo B. And that might be a more</p> <p>22 accurate way to be a study. As you know, there are</p> <p>23 very few of -- of those out here for that.</p> <p>24 Articles are other things such as book</p> <p>25 chapters, descriptions of how the pharmacology of</p> | <p style="text-align: right;">244</p> <p>1 deposition. The time is 2:56 p.m.</p> <p>2 (Deposition concluded at 2:56 p.m.)</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7 <u>NEAL A. SHER, M.D.</u></p> <p>8</p> <p>9 Subscribed and sworn to before me</p> <p>10 this ____ day of _____, 2009.</p> <p>11</p> <p>12</p> <p>13 <u>Notary Public</u></p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |
| <p style="text-align: right;">243</p> <p>1 something works, the -- the other material that I gave</p> <p>2 you in that list of things that I reviewed. I don't</p> <p>3 think I can answer it any better.</p> <p>4 Q. Well, I just want to be clear, Doctor, because</p> <p>5 you used the term "studies." And I just want to</p> <p>6 understand when you use the term "studies," you were</p> <p>7 using it interchangeable with a published article; is</p> <p>8 that correct?</p> <p>9 A. Yeah. Yeah. So if you took it to mean</p> <p>10 something different, my language needs to be slightly</p> <p>11 more precise.</p> <p>12 Q. Okay.</p> <p>13 A. And so we'll say the articles and material out</p> <p>14 there that are published.</p> <p>15 MR. HOPPER: Literature.</p> <p>16 THE WITNESS: Literature.</p> <p>17 MS. LESKIN: Okay. Nothing further.</p> <p>18 SPECIAL MASTER BORG: Anything else?</p> <p>19 MR. OVERHOLTZ: That's it.</p> <p>20 THE VIDEOGRAPHER: Is that the end of the</p> <p>21 deposition?</p> <p>22 SPECIAL MASTER BORG: That's the end.</p> <p>23 MS. LESKIN: Thank you.</p> <p>24 THE VIDEOGRAPHER: For identification, this is</p> <p>25 the end of Videotape 3 and the videotaped</p> | <p style="text-align: right;">245</p> <p>1 CERTIFICATE OF OATH</p> <p>2</p> <p>3 STATE OF FLORIDA)</p> <p>4 COUNTY OF COLLIER)</p> <p>5</p> <p>6 I, the undersigned authority, certify that NEAL A.</p> <p>7 SHER, M.D., personally appeared before me and was duly</p> <p>8 sworn.</p> <p>9 WITNESS my hand and official seal this 20th day of</p> <p>10 February, 2009.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15 <u>Deborah A. Krotz, CSR, RPR, CRR</u></p> <p>16 Notary Public - State of Florida</p> <p>17 My Commission No: DD 405852</p> <p>18 Expires: 3/10/09</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |

62 (Pages 242 to 245)

246

1 REPORTER'S DEPOSITION CERTIFICATE

2
3 STATE OF FLORIDA)
4 COUNTY OF COLLIER)5
6 I, Deborah A. Krotz, Certified Shorthand Reporter,
7 Registered Professional Reporter, Certified Realtime
8 Reporter, and Notary Public in and for the State of
9 Florida at Large, certify that I was authorized to and
10 did stenographically report the deposition of NEAL A.
11 SHER, M.D.; that a review of the transcript was not
12 requested and that the transcript is a true and
13 complete record of my stenographic notes.14 I further certify that I am not a relative,
15 employee, attorney, or counsel of any of the parties,
16 nor am I a relative or employee of any of the parties'
17 attorney or counsel connected with the action, nor am I
18 financially interested in the action.19 DATED this 20th day of February, 2009.
2021
22 _____
23 Deborah A. Krotz, CSR, RPR, CRR
24
25

247

1 ERRATA SHEET
2 VERITEXT REPORTING COMPANY
3 1350 BROADWAY
4 NEW YORK, NEW YORK 10018
5 212-279-94246 CASE: VIAGRA PRODUCTS LIABILITY LITIGATION
7 DEPOSITION DATE: FEBRUARY 13, 2009
8 DEPONENT: NEAL A. SHER, M.D.9 PAGE LINE(S) CHANGE REASON
10
11
12
13
14
15
16
17
18
19
20
2122 _____
23 NEAL A. SHER, M.D.24 SUBSCRIBED AND SWORN TO BEFORE ME
25 THIS ____ DAY OF _____, 20__._____
(NOTARY PUBLIC) MY COMMISSION EXPIRES:

63 (Pages 246 to 247)

(212) 279-9424

VERITEXT REPORTING COMPANY
www.veritext.com

(212) 490-3430